TSCA SCOPE

Objective: *To discuss the nexus between TSCA and other statutes.*
Date: *4:15pm, Friday, December 8, 2017*
Location: *3371 EPA East*
Conference Line*: Call in* Ex. 6 Personal Privacy (PP) *Access Code* Ex. 6 Personal Privacy (PP)
Meeting Materials*:*

- *TSCA as a Gap Filler*
- *TSCA Section 2, 3, 6 & 9 and Rule Provisions, re: Risk Evaluation & Unreasonable Risk.*
- *Risk Evaluation Process and Timeline and First 10 Chemicals*
- *Example of Conceptual Models:*
    - *Methylene Chloride (industrial and commercial)*
    - *Methylene Chloride (environmental release & wastes)*
    - *Carbon Tetrachloride*

Agenda

- Welcome and Introductions **(All)**

- OGC's Consensus View: Issues Raised by "Considerations for Risk Evaluations" **(OGC)**
    - Presentation of OGC position(s), including legal vulnerabilities

- Overview of OPPT Risk Evaluation Approach and Conceptual Models

- Perspectives from Other Offices **(OW; OLEM; OECA; OAR)**
    - How Each Office's Respective Provisions Intersect with TSCA's Section 6 Requirements

- Wrap Up and Next Steps **(OCSPP)**

TSCA as Gap-Filler / Deference to Other Statutes

Questions Presented

- To what extent is TSCA a gap-filler? To what extent is TSCA intended to occupy the same space as other statutes?
- In conducting risk evaluations under TSCA sec. 6(b), under what circumstances is it appropriate to find that risk assessment and/or risk management actions taken under a different statute, by another EPA program or another federal agency, are sufficient to either:
    - Exclude a condition of use from the scope of a risk evaluation; or
    - While keeping it in scope, determine at the problem formulation stage that no further analysis of an exposure pathway is needed to find that it presents no unreasonable risk?

Summary of Pertinent TSCA Provisions

- Sec. 6(b)(4)(F)—Requires, among other things, that a risk evaluation integrate and assess available information on hazards and exposures for the conditions of use; not consider costs or other non-risk factors; take into account as applicable duration, intensity, frequency and number of exposures; and describe the weight of the scientific evidence for the identified hazard and exposure.
- Sec. 9(a)—Establishes an inter-agency referral process applicable when the Administrator makes an unreasonable risk finding and determines, in his discretion, that such risk may be prevented or reduced to a sufficient extent by action taken by another federal agency. Once referral occurs, EPA may not take any action under secs. 6(a) or 7 while the other agency considers the risks in the time period specified by the Administrator. If the other agency does not act, then the Administrator shall initiate or complete the sec. 6(a) or 7 action.
- Sec. 9(b)—Establishes an intra-agency coordination process applicable when the Administrator determines that a risk associated with a chemical could be eliminated or reduced to a sufficient extent by EPA actions under other federal laws within the Administrator's jurisdiction. Provides that the Administrator shall use such other authorities to protect against the risk unless he determines, in his discretion, that it is in the public interest to protect against such risk by actions taken under TSCA. In making a public interest determination, the Administrator must consider the relevant risks and a comparison of the costs and efficiencies of taking action under TSCA versus the other statute.
- Sec. 26(h), (i), (k)—Requires that science-based decisions under sec. 6 use information/ methods/etc. consistent with best available science; be based on the weight of the scientific evidence; and take into consideration reasonably available information.

TSCA Legislative History (1976)

- Senate and House committee reports describe TSCA as filling the following "gaps" that existed in the protections provided by other statutes and regulations:
    - premarket review;
    - direct regulation of chemicals (as opposed to discharges/emissions, regulation of which Congress believed may sometimes be a less efficient way to manage hazards than limiting use of the chemical in the first instance);
    - consideration of all the risks, including cumulative impact of all sources of exposure; and

- collection of test data. S. Rep. No. 94-698 at 1-2; H. Rep. No. 94-1341 at 6-7.

- The Senate report explains: "While individual agencies may be authorized to regulate occupational, environmental, or direct consumer hazards with respect to a chemical substance, there is no agency which has the authority to look comprehensively at the hazards associated with the chemical. Existing authority allows the agencies to only look at the hazards within their jurisdiction in isolation from other hazards associated with the same chemical. The bill would grant [EPA] the authority to look at the hazards in total." S. Rep. No. 94-698 at 2.
- The Conference Report explains that sec. 9 is intended "to assure that overlapping or duplicative regulation is avoided while attempting to provide for the greatest possible measure of protection to health and the environment." S. Rep. No. 94-1302 at 84.

Lautenberg Act Legislative History (2015-16)

- The House Report states that the intent of the amendments is to "reinforce TSCA's original purpose of filling gaps in Federal law," citing language in sec. 9(b)(2) to "help the Administrator decide whether using TSCA" is in the public interest particularly when disposal of a chemical substance is already regulated under RCRA. H. Rep. No. 114-176 at 28.
- Debate in the House among Republican members reflects their understanding that "Congress' intent is to avoid duplicative regulation through the TSCA law." 162 Cong. Rec. at H3028.
- The statement from the Senate Democratic members explains that the changes made in the Lautenberg Act as a whole make TSCA unable to "be construed as a 'gap-filler' statutory authority of last resort" except under the express procedures in sec. 9(a). 162 Cong. Rec. at S3517. It states that the language in sec. 9(b)(2) only applies when the Administrator has determined another statute could reduce the risk, and that sec. 9(b) "allows the Administrator substantial discretion to use TSCA nonetheless, and certainly does not reflect that TSCA is an authority of last resort in such cases."
- Senator Vitter stated that, under section 9(b), EPA should use other authorities, such as RCRA, to address disposal risks. S3522 col. 1.

Considerations for Risk Evaluations

- While sec. 9 shows a preference for managing risk under other statutes, it does not speak directly to the risk evaluation process that would precede risk management, and does not resolve the issue of whether a TSCA risk evaluation may decline to assess conditions or use or exposure pathways that are regulated under other statutes.
- A 'no unreasonable risk' finding may be vulnerable to challenge if it is based on an assertion that the risk is already sufficiently managed under another statute/regulatory program, and:
    - That regulatory program does not have a purely risk-based standard equivalent to TSCA's (i.e., it allows consideration of cost or other non-risk factors); or
    - That regulation may be outdated—its risk assessment is inconsistent with currently available information about the chemical, or with best available science.
        - Even if the regulation is relatively recent, there may be vulnerability if it can be argued that the rulemaking record does not comport with the TSCA science, information and analysis requirements, as interpreted in the risk evaluation rulemaking.

- Other statutes/regulatory regimes should be individually assessed to determine whether actions taken under them are sufficient to find, during TSCA problem formulation, that no further assessment of an exposure pathway is needed.
    - RCRA Subtitle C—presents a comparatively strong basis to find that no further assessment is needed
    - RCRA Subtitle D, Safe Drinking Water Act, Clean Water Act—warrant a closer look

Prepared by Environmental Defense Fund based on the text of H.R. 2576, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (June 22, 2016)

Track changes in this version reflect amendments to the Toxic Substances Control Act made by H.R. 2576 as passed by the full House of Representatives on May 24, 2016, and by the full Senate on June 7, 2016, and signed into law by the President on June 22, 2016. Bill Sections 20 ("No Retroactivity") and 21 ("Trevor's Law") are included at the end but not integrated, as they do not amend TSCA.

Note: In several sections, the bill amends TSCA by striking and replacing entire sections or subsections. Where possible, the marked changes below show the amendments integrated with a greater level of detail (to the level of specific words and phrases). In a few places text is marked as having been moved because a provision in the original now appears in a new location, even if the text has changed to some degree.

TOXIC SUBSTANCES CONTROL ACT[1]

[As Amended Through P.L. 114-182, Enacted June 22, 2016]

TITLE I—CONTROL OF TOXIC SUBSTANCES

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

This Act may be cited as the ''Toxic Substances Control Act''.

TABLE OF CONTENTS

TITLE I—CONTROL OF TOXIC SUBSTANCES

SEC. 2. FINDINGS, POLICY, AND INTENT.

(a) FINDINGS.—The Congress finds that—

[1] The Toxic Substances Control Act (15 U.S.C. 2601–2692) consists of Public Law 94–469 (Oct. 11, 1976; 90 Stat. 2003) and the amendments made by subsequent enactments.

(1) human beings and the environment are being exposed each year to a large number of chemical substances and mixtures.

(2) among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of in- jury to health or the environment; and

(3) the effective regulation of interstate commerce in such chemical substances and mixtures also necessitates the regulation of intrastate commerce in such chemical substances and mixtures.

(b) POLICY.—It is the policy of the United States that—

(1) adequate ~~data~~information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such ~~data~~information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures;

(2) adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment, and to take action with respect to chemical substances and mixtures which are imminent hazards; and

(3) authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.

(c) INTENT OF CONGRESS.—It is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes as provided ~~to take~~ under this Act.
[15 U.S.C. 2601]

SEC. 3. DEFINITIONS.

As used in this Act:

(3) The term 'conditions of use' means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

SEC. 6. PRIORITIZATION, RISK EVALUATION, AND REGULATION OF ~~HAZARDOUS~~ CHEMICAL SUBSTANCES AND MIXTURES.

(a) SCOPE OF REGULATION.—If the Administrator ~~finds that there is a reasonable basis to conclude~~ determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents~~, or will present~~ an unreasonable risk of injury to health or the environment, the Administrator shall by rule, and subject to section 18, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance no longer presents such risk~~to protect adequately against such risk using the least burdensome requirements~~:

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(b) Risk Evaluations.—

(1) PRIORITIZATION FOR RISK EVALUATIONS.—

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(A) IDENTIFICATION OF PRIORITIES FOR RISK EVALUATION.—

(i) HIGH-PRIORITY SUBSTANCES.—The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.

(ii) LOW-PRIORITY SUBSTANCES.—The Administrator shall designate a chemical substance as a low- priority substance if the Administrator concludes, based on information sufficient to establish, without consideration of costs or other nonrisk factors, that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance.

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(4) RISK EVALUATION PROCESS AND DEADLINES.—

(A) IN GENERAL.—The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.

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Risk Evaluation Rule §702.47 Unreasonable Risk Determination.

As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses within the scope of the risk evaluation, either in a single decision document or in multiple decision documents

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SEC. 9. RELATIONSHIP TO OTHER FEDERAL LAWS.

(a) LAWS NOT ADMINISTERED BY THE ADMINISTRATOR.—(1)If the Administrator determines ~~has reasonable basis to conclude~~ that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents ~~or will present~~ an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator, under the conditions of use, and determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency—

(A)(i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and

(ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk; and

(B) to respond to the Administrator with respect to the matters described in subparagraph (A).

Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be
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published in the Federal Register. The agency receiving a request under such a report shall make the requested determination, issue the requested order, and make the requested response within such time as the Administrator specifies in the request, but such time specified may not be less than 90 days from the date the request was made. The response of an agency shall be accompanied by a detailed statement of the findings and conclusions of the agency and shall be published in the Federal Register.

(2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either—

(A) issues an order, within the time period specified by the Administrator in the report, declaring that the activity or combination of activities specified in the description of the risk described in the report does not present the risk described in the report, or

(B) responds within the time period specified by the Administrator in the report and initiates, within 90 days of the publication in the Federal Register of the response of the agency under paragraph (1), action under the law (or laws) administered by such agency to protect against such risk associated with such activity or combination of activities, the Administrator may not take any action under section 6(a) or 7 with respect to such risk.

(3) The Administrator shall take the actions described in paragraph (4) if the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which the report was made does not—

(A) issue the order described in paragraph (2)(A) within the time period specified by the Administrator in the report; or

(B)(i) respond under paragraph (1) within the timeframe specified by the Administrator in the report; and

(ii) initiate action within 90 days of publication in the Federal Register of the response described in clause (i).

(4) If an agency to which a report is submitted under paragraph (1) does not take the actions described in subparagraph (A) or (B) of paragraph (3), the Administrator shall—

(A) initiate or complete appropriate action under section 6; or

(B) take any action authorized or required under section 7, as applicable.

(5) This subsection shall not relieve the Administrator of any obligation to take any appropriate action under section 6(a) or 7 to address risks from the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or any combination of those activities, that are not identified in a report issued by the Administrator under paragraph (1).

(6~~3~~) If the Administrator has initiated action under section 6(a) or 7 with respect to a risk associated with a chemical substance or mixture which was the subject of a report made to an agency under paragraph (1), such agency shall before taking action under the law (or laws) administered by it to protect against such risk consult with the Administrator for the purpose of avoiding duplication of Federal action against such risk.

(b) LAWS ADMINISTERED BY THE ADMINISTRATOR.—(1) The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed

on the Administrator by such other Federal laws.

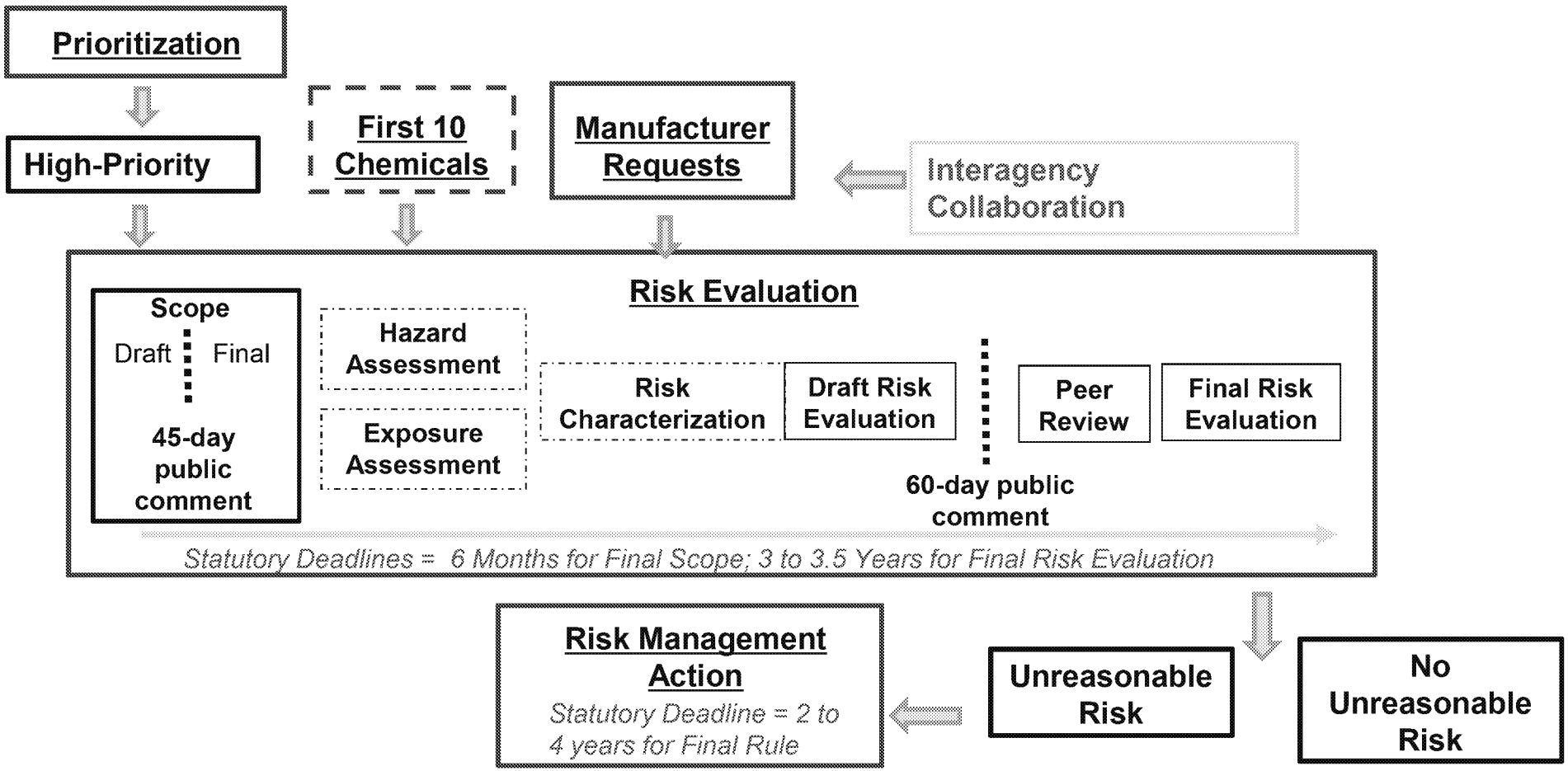
(2) ~~If the Administrator determines that a risk of injury to health or~~ the environment ~~could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not promulgate a rule under subsection (a) to protect against such risk of injury unless the Administrator finds, in the Administrator's discretion,~~ In making a determination under paragraph (1) that it is in the public interest for the Administrator to take an action under this title with respect to a chemical substance or mixture rather than under another law administered in whole or in part by the Administrator, ~~to protect against such risk under this Act. In making such a finding~~ the Administrator shall consider, based on information reasonably available to the Administrator, ~~(i)~~ all relevant aspects of the risk described in paragraph (1)~~, as determined by the Administrator in the Administrator's discretion, (ii)~~ and a comparison of the estimated costs ~~of complying with actions taken under this Act and under such law (or laws), and (iii) the relative~~ and efficiencies~~y~~ of the actions to be taken under this title ~~Act~~ and an action to be taken under such other law ~~(or laws)~~ to protect against such risk ~~of injury~~.

(c) OCCUPATIONAL SAFETY AND HEALTH.—In exercising any authority under this Act, the Administrator shall not, for purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970, be deemed to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety and health.

(d) COORDINATION.—In administering this Act, the Administrator shall consult and coordinate with the Secretary of Health and Human Services~~, Education, and Welfare~~ and the heads of any other appropriate Federal executive department or agency, any relevant independent regulatory agency, and any other appropriate instrumentality of the Federal Government for the purpose of achieving the maximum enforcement of this Act while imposing the least burdens of duplicative requirements on those subject to the Act and for other purposes. The Administrator shall, in the report required by section 30, report annually to the Congress on actions taken to coordinate with such other Federal departments, agencies, or instrumentalities, and on actions taken to coordinate the authority under this Act with the authority granted under other Acts referred to in subsection (b).

(e) EXPOSURE INFORMATION.—In addition to the requirements of subsection (a), if the Administrator obtains information related to exposures or releases of a chemical substance or mixture that may be prevented or reduced under another Federal law, including a law not administered by the Administrator, the Administrator shall make such information available to the relevant Federal agency or office of the Environmental Protection Agency.
[15 U.S.C. 2608]

Risk Evaluation Process and Timeline



Initial 10 Risk Evaluations

- The list of the initial 10 chemicals was published on Dec. 19, 2016

1, 4 Dioxane
1-Bromopropane
Asbestos
Carbon Tetrachloride
Cyclic Aliphatic Bromide Cluster (HBCD)
Methylene Chloride
N-Methylpyrolidone
Pigment Violet 29
Trichloroethylene
Tetrachloroethylene

- Scope documents published June 22, 2017

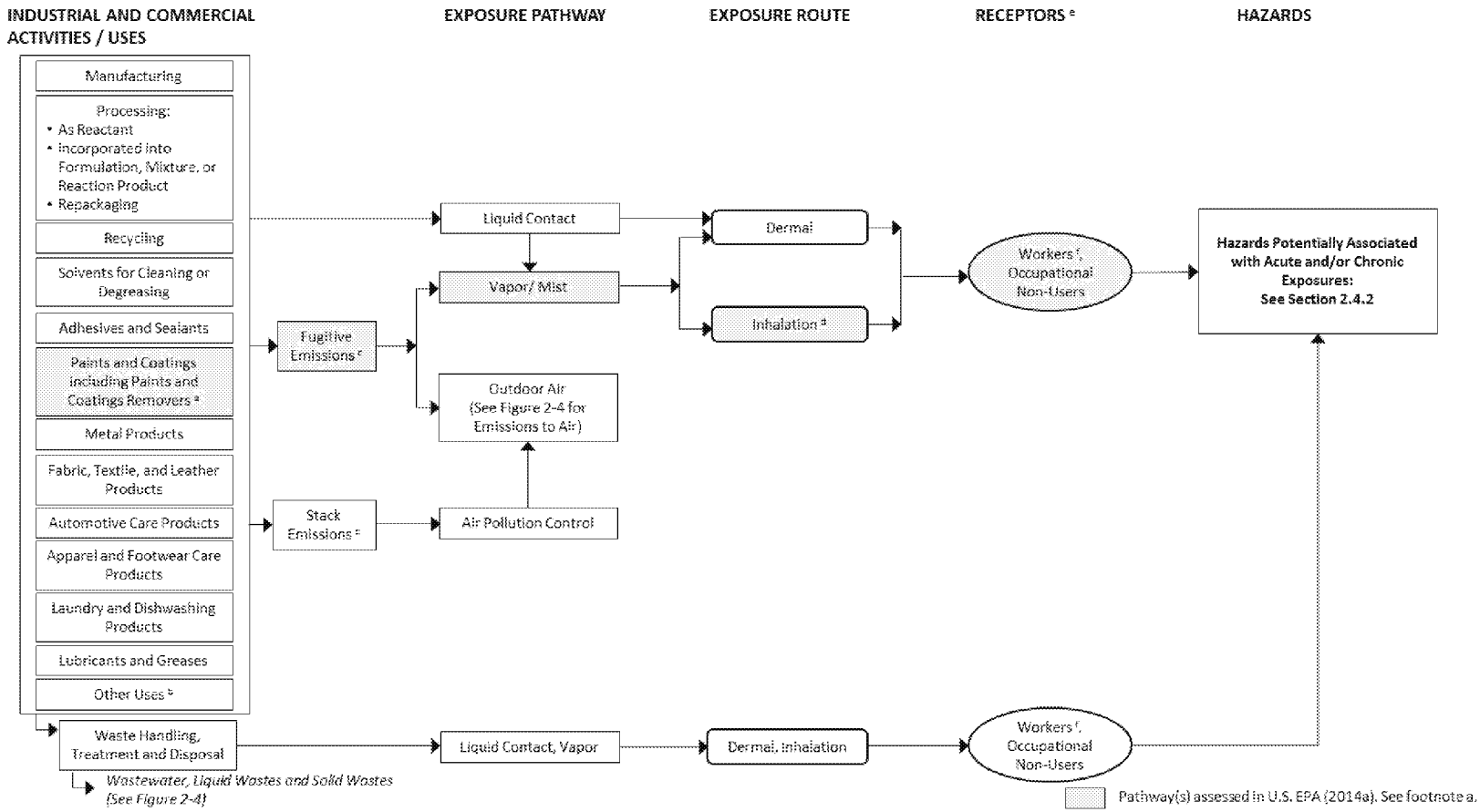


Figure 2-2. Initial Methylene Chloride Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of methylene chloride.

[a] U.S. EPA (2014a) assessed paint removal uses in industrial and commercial settings and therefore those uses are out of scope for the risk evaluation.

[b] Some products are used in both commercial and consumer applications such adhesives and sealants. Additional uses of methylene chloride are included in Table 2-3.

[c] Stack air emissions are emissions that occur through stacks, confined vents, ducts, pipes or other confined air streams. Fugitive air emissions are those that are not stack emissions and include fugitive equipment leaks from valves, pump seals, flanges, compressors, sampling connections and open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation systems.

[d] Exposure may occur through mists that deposit in the upper respiratory tract and are swallowed.

[e] Receptors include potentially exposed or susceptible subpopulations.

[f] When data and information are available to support the analysis, EPA also considers the effect that engineering controls and/or personal protective equipment have on occupational exposure levels.

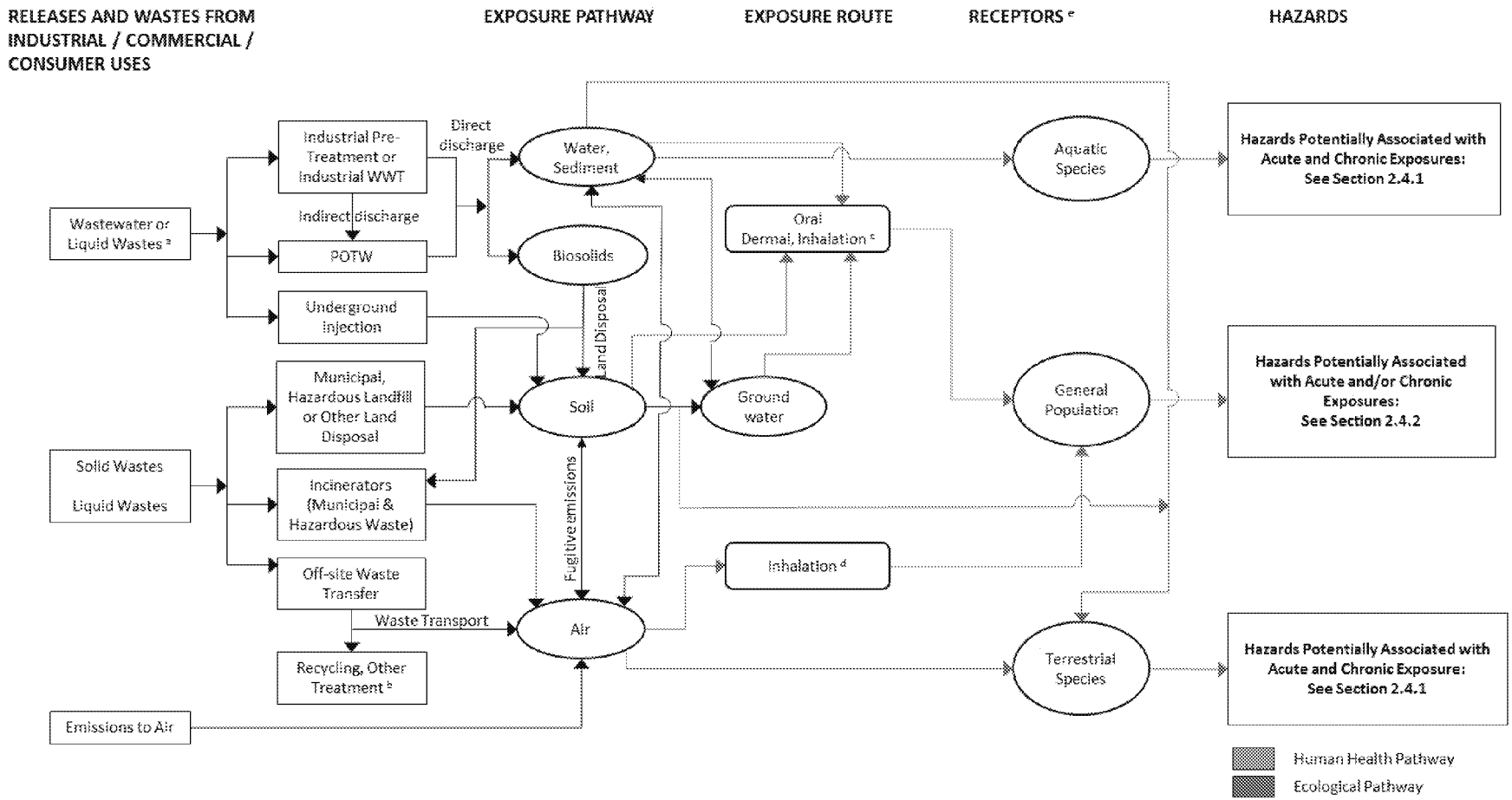


Figure 2-4. Initial Methylene Chloride Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from environmental releases and wastes of methylene chloride.

[a] Industrial wastewater may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, wastewater may be released directly to POTW (i.e., down the drain). Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water.

[b] Additional releases may occur from recycling and other waste treatment.

[c] Volatilization from or liquid contact with tap water in the home during showering, bathing, washing, etc. represents another potential in-home exposure pathway.

[d] Presence of mist is not expected; dermal and oral exposures are negligible.

[e] Receptors include potentially exposed or susceptible subpopulations.

Methylene Chloride Regulatory Landscape

Methylene Chloride is subject to the following EPA-administered statutes/sections

Office of Air

1. Clean Air Act (CAA) – Section 112(b)
   Lists methylene chloride as a HAP (42 U.S. Code section 7412), and is considered an "urban air toxic" (CAA Section 112(k)).

2. CAA – Section 112(d)
   There are 16[1] source-specific NESHAPs for methylene chloride and 15 Risk and Technology Reviews completed for methylene chloride.

3. Clean Air Act – Section 612
   Under the SNAP program, EPA listed methylene chloride as an acceptable substitute in multiple industries, including in foam blowing agents for polyurethane, in cleaning solvents, in aerosol solvents and in adhesives and coatings (1994). In 2016, methylene chloride was listed as an unacceptable substitute for use in flexible polyurethane.

Office of Water

4. Clean Water Act – Section 304(a)
   Under section 304(a), methylene chloride has a national recommended human health ambient water quality criteria.

5. Clean Water Act – Section 307(a)
   Methylene chloride is designated as a toxic pollutant under section 307(a)(1) of the CWA and as such is subject to best available technology effluent limitations established on either a national basis through rules (Sections 301(b), 304(b), 307(b), 306) or on a case-by-case best professional judgement basis in NPDES permits (Section 402(a)(1)(B)).

6. Safe Drinking Water Act – Section 1412
   Methylene chloride is subject to NPDWR under the SDWA with a MCLG of zero and an enforceable MCL of 0.005 mg/L or 5 ppb (Section 1412).

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[1] Flexible polyurethane foam production and fabrication process; Aerospace +RTR; Boat manufacturing; Chemical manufacturing industry (agricultural chemicals and pesticides, cyclic crude and intermediate production, industrial inorganic chemicals, industrial and miscellaneous organic chemicals, inorganic pigments, plastic materials and resins, pharmaceutical production, synthetic rubber); Fabric printing, coating and dyeing; Halogenated Solvent Cleaning + RTR; Miscellaneous organic chemical production and processes (MON); Paint and allied products manufacturing (area sources); Paint stripping and miscellaneous surface coating operations (area sources); Paper and other web surface coating; Pesticide active ingredient production +RTR; Pharmaceutical production; Publicly Owned Treatment Works + RTR; Reciprocating Internal Combustion Engines (RICE); Reinforced plastic composites production; Wood preserving (area sources).

Office of Land and Emergency Response

7. Resource Conservation and Recovery Act (RCRA) – Section 3001
   Methylene chloride is included on the list of hazardous wastes pursuant to RCRA 3001. RCRA Hazardous Waste Code: F001, F002; U080. In 2013, EPA modified its hazardous waste management regulations to conditionally exclude solvent-contaminated wipes that have been cleaned and reused from the definition of solid waste under RCRA (78 FR 46447 July 31, 2013, 40 CFR 261.4(a)(26)).

8. Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) – Sections 102(a) and 103
   Methylene chloride is a hazardous substance under CERCLA. Releases of methylene chloride in excess of 1,000 pounds must be reported (40 CFR 302.4).

Office of Pollution Prevention and Toxics

9. Emergency Planning and Community Right-to-Know (EPCRA); Section 313
   Methylene chloride is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 01, 1987.

10. Federal Food, Drug, and Cosmetic Act (FFDCA) – Section 408
    Methylene chloride was registered as antimicrobial, conventional chemical in 1974, but this tolerance was revoked in 2002, and there are currently no registrations for use as a pesticide (67 FR 16027, April 4, 2002).

11. Toxic Substances Control Act – Sections 4 [test rules], 6 [proposed rule on paint strippers]; 8(a)[CDR], 8(b)[TSCA inventory], 8(d)[health& safety studies], 8(e)[information about substantial risk]

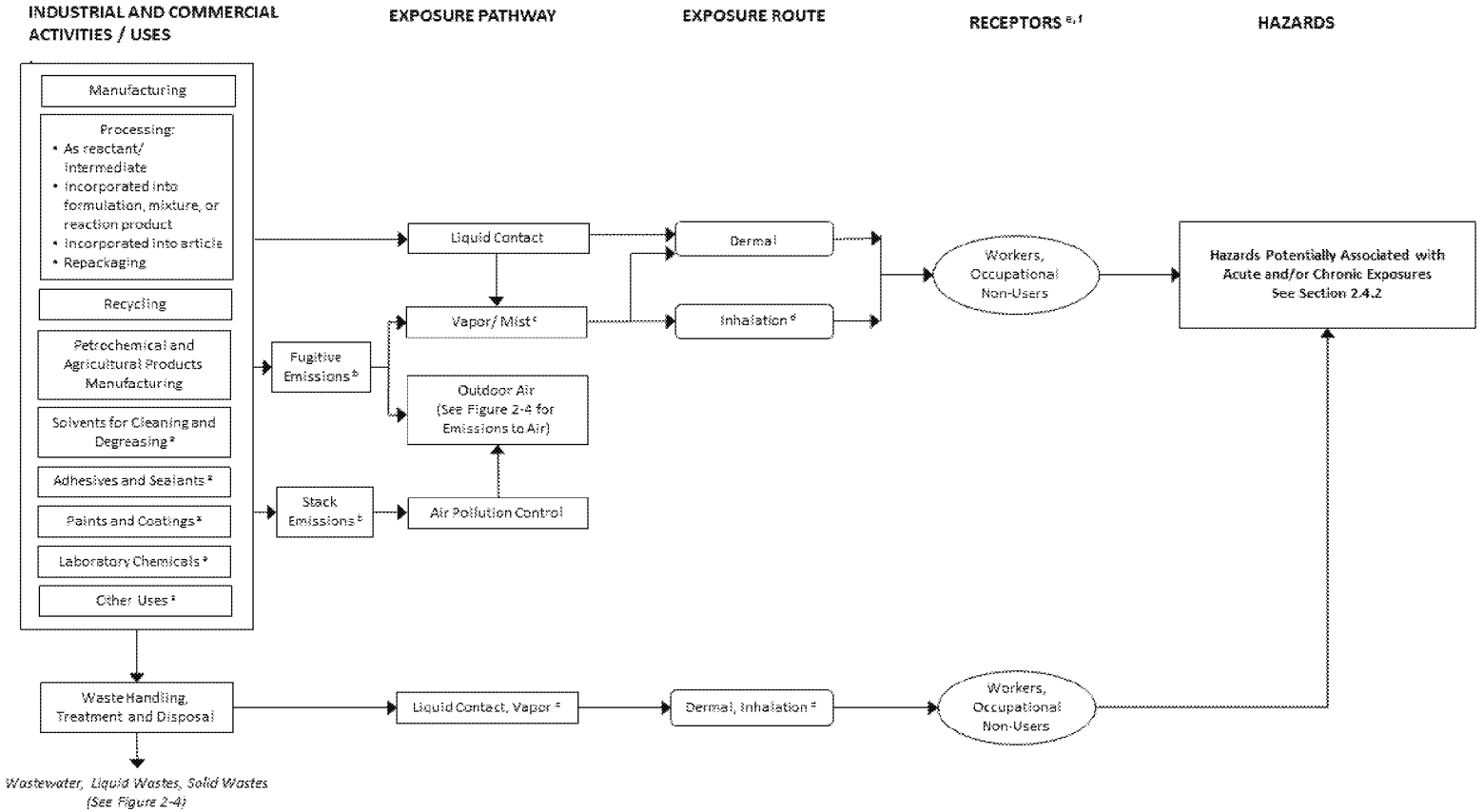

Figure 2-2. Initial Carbon Tetrachloride Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of carbon tetrachloride.

[a] Some products are used in both commercial and consumer applications. Additional uses of carbon tetrachloride are included in Table 2-3.

[b] Stack air emissions are emissions that occur through stacks, confined vents, ducts, pipes or other confined air streams. Fugitive air emissions are those that are not stack emissions, and include fugitive equipment leaks from valves, pump seals, flanges, compressors, sampling connections, open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation systems.

[c] Includes possible vapor intrusion into industrial or commercial facility from carbon tetrachloride contaminated soil and/or ground water.

[d] Exposure through mists that deposit in the upper respiratory tract and are swallowed.

[e] Receptors include potentially exposed or susceptible subpopulations.

[f] When data and information are available to support the analysis, EPA also considers the effect that engineering controls and/or personal protective equipment have on occupational exposure levels.

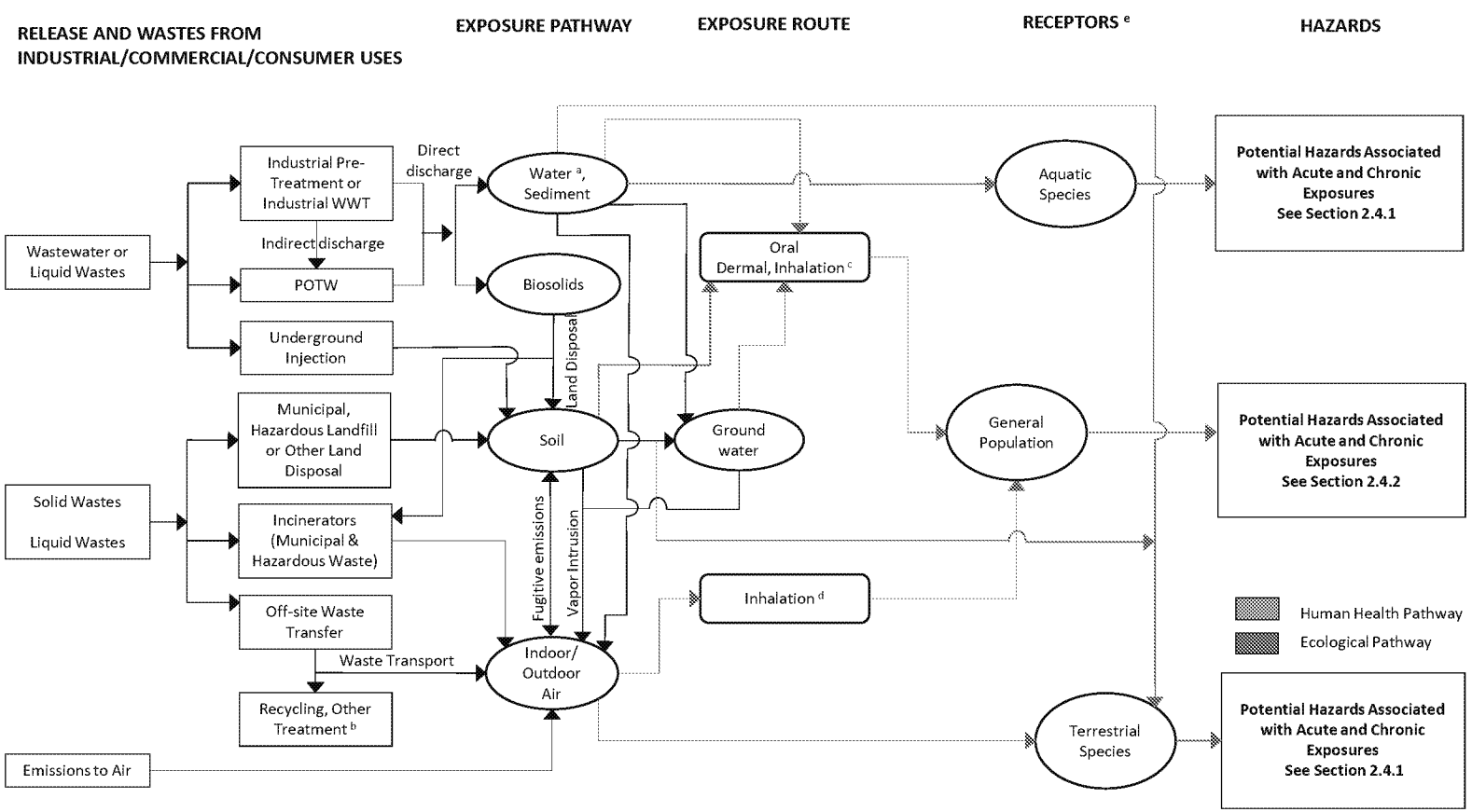

Figure 2-4. Initial Carbon Tetrachloride Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from environmental releases and wastes of carbon tetrachloride.

[a] Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to publicly owned treatment works (POTW) (indirect discharge). For consumer uses, such wastes may be released directly to POTW (i.e., down the drain). Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water.

[b] Additional releases may occur from recycling and other waste treatment.

[c] Volatilization from or liquid contact with tap water in the home during showering, bathing, washing, etc. represents another potential in-home exposure pathway.

[d] Presence of mist is not expected; dermal and oral exposure are negligible.

[e] Receptors include potentially exposed or susceptible subpopulations.

APPENDICES

Appendix A REGULATORY HISTORY

A.1 Federal Laws and Regulations

Table_Apx A-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
EPA Regulations		
TSCA - Section 6(b)	EPA is directed to identify and begin risk evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.	Carbon tetrachloride is on the initial list of chemicals to be evaluated for unreasonable risk under TSCA (81 FR 91927, December 19, 2016).
TSCA - Section 8(a)	The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	Carbon tetrachloride manufacturing (including importing), processing and use information is reported under the CDR Rule (76 FR 50816, August 16, 2011).
TSCA - Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical substance manufactured, processed, or imported in the United States.	Carbon tetrachloride was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process under TSCA section 5 (60 FR 16309, March 29, 1995).
TSCA - Section 8(d)	Provides EPA with authority to issue rules requiring producers, importers and (if specified) processors of a chemical substance or mixture to submit lists and/or copies of health and safety studies.	Two submissions received (1947-1994) (U.S. EPA, ChemView. Accessed April 13, 2017).
TSCA - Section 8(e)	Manufacturers (including imports), processors and distributors must immediately notify EPA if they obtain information that supports the conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment.	Three submissions received (1992-2010) (U.S. EPA, ChemView. Accessed April 13, 2017).
TSCA - Section 4	Provides EPA with authority to issue rules and orders requiring	Seven section 4 notifications received for carbon tetrachloride:

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	manufacturers (including importers) and processors to test chemical substances and mixtures.	two acute aquatic toxicity studies, one bioaccumulation report and four monitoring reports (1978-1980) (U.S. EPA, ChemView. Accessed April 13, 2017).
EPCRA - Section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full time equivalent employees and that manufacture, process, or otherwise use a TRI-listed chemical in quantities above threshold levels.	Carbon tetrachloride is a listed substance subject to reporting requirements under 40 CFR 372.65 effective as of January 1, 1987.
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) - Sections 3 and 6	FIFRA governs the sale, distribution and use of pesticides. Section 3 of FIFRA generally requires that pesticide products be registered by EPA prior to distribution or sale. Pesticides may only be registered if, among other things, they do not cause "unreasonable adverse effects on the environment." Section 6 of FIFRA provides EPA with the authority to cancel pesticide registrations if either (1) the pesticide, labeling, or other material does not comply with FIFRA; or (2) when used in accordance with widespread and commonly recognized practice, the pesticide generally causes unreasonable adverse effects on the environment.	Use of carbon tetrachloride as a grain fumigant was banned under FIFRA in 1986 (51 FR 41004, November 12, 1986).
Federal Food, Drug, and Cosmetic Act (FFDCA) - Section 408	FFDCA governs the allowable residues of pesticides in food. Section 408 of the FFDCA provides EPA with the authority to set tolerances (rules that establish maximum allowable residue limits), or exemptions from the requirement of a tolerance, for all residues of a pesticide (including both active and inert ingredients) that are in or on food. Prior to issuing a tolerance or exemption from tolerance, EPA must determine that the tolerance or exemption is "safe." Sections 408(b) and (c) of the FFDCA define "safe" to mean the Agency has a	EPA removed carbon tetrachloride from its list of pesticide product inert ingredients used in pesticide products in 1998 (63 FR 34384, June 24, 1998).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	reasonable certainty that no harm will result from aggregate exposures to the pesticide residue, including all dietary exposure and all other exposure (e.g., non-occupational exposures) for which there is reliable information. Pesticide tolerances or exemptions from tolerance that do not meet the FFDCA safety standard are subject to revocation. In the absence of a tolerance or an exemption from tolerance, a food containing a pesticide residue is considered adulterated and may not be distributed in interstate commerce.	
CAA - Section 112(b)	This section lists 189 HAPs that must be addressed by EPA and includes authority for EPA to add or delete pollutants. EPA may, by rule, add pollutants that present, or may present, a threat of adverse human health effects or adverse environmental effects.	Lists carbon tetrachloride as a HAP (70 FR 75047, December 19, 2005).
CAA - Section 112(d)	Directs EPA to establish, by rule, NESHAPs for each category or subcategory of major sources and area sources of HAPs. The standards must require the maximum degree of emission reduction that EPA determines is achievable by each particular source category. This is generally referred to as maximum achievable control technology (MACT).	There are a number of source-specific NESHAPs for carbon tetrachloride, including: Rubber tire manufacturing (67 FR 45588, July 9, 2002) Chemical Manufacturing Area Sources (74 FR 56008, October 29, 2009) Use of carbon tetrachloride as a dilutent for NCl3 (59 FR 19402, April 22,1994), Halogenated solvent cleaning operations (59 FR 61801, December 2, 1994) Wood Furniture Manufacturing Operations (60 FR 62930, December 7,1995) Group 1 Polymers and Resins (61 FR 46906, September 5, 1996)

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
		Plywood and Composite Wood Products (69 FR 45944, July 30, 2004)
CAA - Section 604	Establishes a mandatory phase-out of ozone depleting substances.	The production and import of most Class I Ozone Depleting Substances (ODS), including carbon tetrachloride, was banned in 1996 (58 FR 65018, December 10, 1993). However, this ban does not apply to production and import of amounts that are transformed. 40 CFR 82.4. "Transform" is defined as "to use and entirely consume (except for trace quantities) a controlled substance in the manufacture of other chemicals for commercial purposes." 40 CFR 82.3.
CWA - Section 304(a)(1)	Requires EPA to develop and publish ambient water quality criteria (AWQC) reflecting the latest scientific knowledge on the effects on human health that may be expected from the presence of pollutants in any body of water.	In 2015, EPA published updated AWQC for carbon tetrachloride, including recommendations for "water + organism" and "organism only" human health criteria for states and authorized tribes to consider when adopting criteria into their water quality standards.
CWA – Sections 301(b), 304(b), 306, and 307(b)	Requires establishment of Effluent Limitations Guidelines and Standards for conventional, toxic, and non-conventional pollutants. For toxic and non-conventional pollutants, EPA identifies the best available technology that is economically achievable for that industry after considering statutorily prescribed factors and sets regulatory requirements based on the performance of that technology.	
CWA - Section 307(a)	Establishes a list of toxic pollutants or combination of pollutants under the CWA. The statute specifies a list of families of toxic pollutants also listed in the Code of Federal Regulations at 40 CFR 401.15. The "priority pollutants" specified by those families are listed in	Carbon tetrachloride is designated as a toxic pollutant under section 307(a)(1) of the CWA and as such is subject to effluent limitations per section 1317 of the Clean Water Act.

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	40 CFR part 423, Appendix A. These are pollutants for which best available technology effluent limitations must be established on either a national basis through rules, see section 301(b), 304(b), 307(b), 306, or on a case-by-case best professional judgment basis in NPDES permits. CWA 402(a)(1)(B).	
SDWA - Section 1412	Requires EPA to publish a non-enforceable maximum contaminant level goals (MCLGs) for contaminants which 1. may have an adverse effect on the health of persons; 2. are known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and 3. in the sole judgment of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reductions for persons served by public water systems. When EPA publishes an MCLG, EPA must also promulgate a National Primary Drinking Water Regulation (NPDWR) which includes either an enforceable maximum contaminant level (MCL), or a required treatment technique. Public water systems are required to comply with NPDWRs.	Carbon tetrachloride is subject to National Primary Drinking Water Regulations (NPDWR) under SDWA and EPA has set a MCLG of zero and an enforceable MCL of 0.005 mg/L (56 FR 3526 January 30, 1991).
Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) - Sections 102(a) and 103	Authorizes EPA to promulgate regulations designating as hazardous substances those substances which, when released into the environment, may present substantial danger to the public health or welfare or the environment. EPA must also promulgate regulations establishing the quantity of any hazardous substance the release of which must be reported under Section 103. Section 103 requires persons in charge of vessels or facilities to report to the National Response Center if they	Carbon tetrachloride is a hazardous substance under CERCLA. Releases of carbon tetrachloride in excess of 10 pounds must be reported (40 CFR 302.4).

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	have knowledge of a release of a hazardous substance above the reportable quantity threshold.	
RCRA - Section 3001	Directs EPA to develop and promulgate criteria for identifying the characteristics of hazardous waste, and for listing hazardous waste, taking into account toxicity, persistence, and degradability in nature, potential for accumulation in tissue, and other related factors such as flammability, corrosiveness, and other hazardous characteristics.	Carbon tetrachloride is included on the list of hazardous wastes pursuant to RCRA 3001. Two categories of carbon tetrachloride wastes are considered hazardous: discarded commercial chemicals (U211) (40 CFR 261.31(a)), and spent degreasing solvent (F001) (40 CFR 261.33(f)) (45 FR 33084 May 19, 1980). RCRA solid waste that leaches 0.5 mg/L or more carbon tetrachloride when tested using the TCLP leach test is RCRA hazardous (D019) under 40 CFR 261.24 (55 FR 11798 March 29, 1990). In 2013, EPA modified its hazardous waste management regulations to conditionally exclude solvent-contaminated wipes that have been cleaned and reused from the definition of solid waste under RCRA (40 CFR 261.4(a)(26)) (78 FR 46447, July 31, 2013).
Other Federal Regulations		
Federal Hazardous Substance Act (FHSA)	Requires precautionary labeling on the immediate container of hazardous household products and allows the Consumer Product Safety Commission (CPSC) to ban certain products that are so dangerous or the nature of the hazard is such that required labeling is not adequate to protect consumers.	Use of carbon tetrachloride in consumer products was banned in 1970 by the CPSC (16 CFR 1500.17).
FFDCA	Provides the U.S. Food and Drug Administration (FDA) with authority to	The FDA regulates carbon tetrachloride in bottled water. The maximum permissible level of

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	oversee the safety of food, drugs and cosmetics.	carbon tetrachloride in bottled water is 0.005 mg/L (21 CFR 165.110). All medical devices containing or manufactured with carbon tetrachloride must contain a warning statement that the compound may destroy ozone in the atmosphere (21 CFR 801.433). Carbon tetrachloride is also listed as an "Inactive Ingredient for approved Drug Products" by FDA (FDA Inactive Ingredient Database. Accessed April 13, 2017).
OSHA	Requires employers to provide their workers with a place of employment free from recognized hazards to safety and health, such as exposure to toxic chemicals, excessive noise levels, mechanical dangers, heat or cold stress, or unsanitary conditions. Under the Act, OSHA can issue occupational safety and health standards including such provisions as PELs, exposure monitoring, engineering and administrative control measures, and respiratory protection.	In 1970, OSHA issued occupational safety and health standards for carbon tetrachloride that included a PEL of 10 ppm TWA, exposure monitoring, control measures and respiratory protection (29 CFR 1910.1000). OSHA prohibits all workplaces from using portable fire extinguishers containing carbon tetrachloride (29 CFR 1910.157(c)(3)).
Atomic Energy Act	The Atomic Energy Act authorizes the Department of Energy to regulate the health and safety of its contractor employees.	10 CFR 851.23, Worker Safety and Health Program, requires the use of the 2005 ACGIH TLVs if they are more protective than the OSHA PEL. The 2005 TLV for carbon tetrachloride is 5 ppm (8hr Time Weighted Average) and 10 ppm Short Term Exposure Limit (STEL).

A.2 State Laws and Regulations

Table_Apx A-2. State Laws and Regulations

State Actions	Description of Action
State agencies of interest	
State permissible exposure limits	California PEL: 12.6 mg/L (Cal Code Regs. Title 8, section 5155), Hawaii PEL: 2 ppm (Hawaii Administrative Rules section 12-60-50).
State Right-to-Know Acts	Massachusetts (454 Code Mass. Regs. section 21.00), New Jersey (8:59 N.J. Admin. Code section 9.1), Pennsylvania (34 Pa. Code section 323).
State air regulations	Allowable Ambient Levels (AAL): Rhode Island (12 R.I. Code R. 031-022), New Hampshire (RSA 125-I:6, ENV-A Chap. 1400).
State drinking water standards and guidelines	Arizona (14 Ariz. Admin. Register 2978, August 1, 2008), California (Cal Code Regs. Title 26, section 22-64444), Delaware (Del. Admin. Code Title 16, section 4462), Connecticut (Conn. Agencies Regs. section 19-13-B102), Florida (Fla. Admin. Code R. Chap. 62-550), Maine (10 144 Me. Code R. Chap. 231), Massachusetts (310 Code Mass. Regs. section 22.00), Minnesota (Minn R. Chap. 4720), New Jersey (7:10 N.J Admin. Code section 5.2), Pennsylvania (25 Pa. Code section 109.202), Rhode Island (14 R.I. Code R. section 180-003), Texas (30 Tex. Admin. Code section 290.104).
Other	In California, carbon tetrachloride was added to the Proposition 65 list in 1987 (Cal. Code Regs. Title 27, section 27001). Carbon tetrachloride is on the MA Toxic Use Reduction Act (TURA) list of 1989 (301 Code Mass. Regs. section 41.03).

A.3 International Laws and Regulations

Table_Apx A-3. Regulatory Actions by Other Governments and Tribes

Country/Organization	Requirements and Restrictions
Regulatory Actions by other Governments and Tribes	
Montreal Protocol	Carbon tetrachloride is considered an ODS and its production and use are controlled under the 1987 Montreal Protocol on Substances That Deplete the Ozone Layer and its amendments (Montreal Protocol Annex B – Group II).

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families on Risk Evaluation Scoping Documents for Ten Chemical Substances under the Toxic Substances Control Act

Submitted via Regulations.gov (September 19, 2017)

1,4-Dioxane. Docket ID No.: EPA-HQ-OPPT-2016-0723.

1-Bromopropane. Docket ID No.: EPA-HQ-OPPT-2016-0741.

Asbestos. Docket ID No.: EPA-HQ-OPPT-2016-0736.

Carbon Tetrachloride. Docket ID No.: EPA-HQ-OPPT-2016-0733.

Cyclic Aliphatic Bromide Cluster (Hexabromocyclododecane or HBCD). Docket ID No.: EPA-HQ-OPPT-2016-0735.

Methylene Chloride. Docket ID No.: EPA-HQ-OPPT-2016-0742.

N-Methylpyrrolidone (NMP). Docket ID No.: EPA-HQ-OPPT-2016-0743.

Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f]diisoquinoline-1,3,8,10(2H,9H)-tetrone). Docket ID No.: EPA-HQ-OPPT-2016-0725.

Trichloroethylene (TCE). Docket ID No.: EPA-HQ-OPPT-2016-0737.

Tetrachloroethylene (also known as Perchloroethylene). Docket ID No.: EPA-HQ-OPPT-2016-0732.

INTRODUCTION AND SUMMARY

Safer Chemicals, Health Families (SCHF), Earthjustice, Natural Resources Defense Council (NRDC), Environmental Health Strategy Center, Toxic-Free Future and Asbestos Disease Awareness Organization (ADAO) submit these comments on the scoping documents developed by the Environmental Protection Agency (EPA) on the initial 10 chemicals selected for risk evaluations under the newly enacted Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). These organizations are committed to enhancing the safety of chemicals used in homes, workplaces and products and strongly support effective and health-protective implementation of the LCSA.

Through LCSA, Congress amended the Toxic Substances Control Act (TSCA) to establish a new framework for conducting timely, comprehensive and science-based risk evaluations for chemicals of concern. The law provides that EPA's evaluations must be strictly risk-based and must result in a definitive determination of whether the evaluated substance as a whole presents an unreasonable risk of injury to health and the environment across its life cycle, without regard to cost and other non-risk factors.

Congress wanted EPA to launch the risk evaluation process expeditiously. Accordingly, in section 6(b)(2)(A) of TSCA, it directed EPA to assure that evaluations are initiated within six months of the law's enactment on 10 substances drawn from the 2014 TSCA Workplan list. EPA designated these 10 substances on December 19, 2016,[1] and following a public meeting and comment period, released draft scoping documents on June 22. Soon thereafter, EPA announced that it was developing problem formulation documents on the 10 chemicals and would release them for further comment by the end of the year. It also requested comments on the scoping documents in order to inform its approach to problem formulation.[2]

These comments address general issues common to the 10 chemicals as well as several chemical-specific issues. We are submitting our comments to all ten of the EPA dockets. The comments build on earlier submissions by these groups, including our March 15 comments on the scoping process and our July 24 letter to the Agency providing initial reactions to the 10 scoping documents. We have coordinated with a number of other public health and scientific organizations in developing comments on the scoping documents and generally support their recommendations.

The main messages and key recommendations in our comments are as follows:

- Problem formulation can fill gaps in scoping documents and enhance their depth of analysis but cannot be used to remove uses, exposures and hazards from the risk evaluation scope
- EPA should use problem formulation to provide more detail on the potentially exposed and susceptible subpopulations it will consider and how risks to these subpopulations will be determined
- Problem formulations should also describe EPA's strategies for assessing risks from aggregate and cumulative exposures
- Ongoing use and disposal of chemical products that are no longer being manufactured fall within the TSCA definition of "conditions of use" and must be included in problem formulations and assessed in risk evaluations
- Chemicals with ozone depletion and global warming potential pose environmental and health risks that fall within the scope of TSCA risk evaluations
- EPA risk evaluations should not reassess uses of trichloroethylene (TCE), methylene chloride (MC) and N-Methylpyrrolidone (NMP) that were fully assessed in its proposed section 6(a) rules, although these exposure pathways should be included in its determinations of aggregate exposure to these chemicals
- In the course of TSCA risk evaluations, EPA should not revisit definitive findings in IRIS assessments since these assessments represent the Agency's authoritative, peer reviewed determinations on the health effects of the chemicals they address
- In evaluating workplace risks, EPA should recognize and account for the uneven use and effectiveness of engineering controls, labeling and personal protective equipment in preventing occupational exposure and determine risks to workers in situations where these measures are not in place or ineffective
- EPA should not exclude from the 1,4-dioxane evaluation its production as a byproduct or impurity, which is a significant source of contamination of water sources and cancer risk

[1] 81 Federal Register 91927
[2] 82 Fed. Reg. 31,592 (July 7, 2017).

- In order to apply these general principles and fill other gaps in its scoping documents, these documents must be expanded and strengthened in several specific respects during problem formulation
- EPA should not prejudge the absence of adverse effects for particular end-points at the scoping stage but should defer such conclusions until the systematic review phase of its risk evaluation as the law requires
- Problem formulations should highlight aspects of use and exposure where available information is insufficient and request or require submission of this information by industry and other interested parties
- EPA needs to take stronger steps to limit CBI treatment of critical information during the risk evaluation process so that transparency and public participation in that process are not impaired

I. PROBLEM FORMULATION CAN FILL GAPS IN SCOPING DOCUMENTS AND ENHANCE THEIR DEPTH OF ANALYSIS BUT CANNOT BE USED TO REMOVE USES, EXPOSURES AND HAZARDS FROM THE RISK EVALUATION SCOPE

The 10 chemicals undergoing risk evaluations have widespread and substantial exposure and multiple adverse health effects. Comprehensive and health protective assessments of their safety are essential to safeguard communities and vulnerable populations and to set a precedent for strong and effective implementation of the new law. For this reason, our groups made a significant investment in characterizing the use and exposure profiles of several of the 10 chemicals and provided extensive submissions to the Agency to help inform its scoping documents for these chemicals.

The scoping documents represent a considerable amount of work in a short period of time and provide a helpful starting point for the 10 evaluations. However, the July 7 Federal Register notice announcing the availability of the scoping documents acknowledges that the Agency was unable to process all the information gathered during the scoping process and that the scoping documents were not as "refined or specific" as EPA had hoped. We agree with this assessment and believe that the scoping documents contain serious gaps, lack sufficient information on use and exposure, impose questionable limitations on the risk scenarios to be examined and fail to provide a roadmap to key elements of assessment methodology. These shortcomings reduce the utility of the scoping documents in laying the groundwork for well-informed and rigorous risk evaluations.

Given their limitations, we believe that expanding and strengthening the scoping documents through a problem formulation process is appropriate in this instance. However, neither LCSA nor the recently promulgated risk evaluation process rule refers to or authorizes problem formulation. Because it has no basis in the law, we oppose using problem formulation to narrow the scope of risk evaluations by deleting conditions of use, exposure pathways or health or environmental end-points identified in the June scoping documents. Section 6(b)(4)(D) of amended TSCA provides that, "not later than 6 months after the initiation of a risk evaluation," EPA must "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and the potentially exposed or susceptible subpopulations the Administrator expects to consider." EPA met this requirement in its June scoping documents. The law provides no basis for EPA to remove uses, hazards or exposures from a risk

evaluation after its scope has been established in accordance with section 6(b)(4)(D).[3] Since problem formulation is not a recognized step in the risk evaluation process or a substitute for scoping under LCSA, it cannot be used narrow a risk evaluation's scope after-the-fact.

We do support, however, using problem formulation to provide more detail on the conditions of use, potentially exposed and susceptible subpopulations, and exposure pathways that EPA will evaluate as well as further explanation of the methodologies that EPA will use in its analysis of these and other risk assessment elements. This will help better structure the risk evaluations, assure that all relevant information is considered, and characterize more fully the conditions of use to be evaluated – without narrowing the risk evaluation scope.

II. EPA SHOULD USE PROBLEM FORMULATION TO PROVIDE MORE DETAIL ON THE POTENTIALLY EXPOSED AND SUSCEPTIBLE SUBPOPULATIONS IT WILL CONSIDER AND HOW RISKS TO THESE SUBPOPULATIONS WILL BE DETERMINED

One area that would benefit from greater elaboration during problem formulation is the identification of potentially exposed or susceptible subpopulations that require consideration in risk evaluations under TSCA section 6(b)(4)(F). The scoping documents provide nearly identical general "boilerplate" descriptions of such subpopulations. Further particulars on the size, geographic location, demographic characteristics and exposure profile of each subpopulation EPA has identified would provide helpful assurance that the risks to that subpopulation will be characterized with the rigor that TSCA requires.

It is also critical for EPA to spell out the methodology it intends to use to determine the nature and magnitude of the risks that chemicals pose to each subpopulation. Such subpopulations are often comprised of low income and/or people of color and exposed to a disproportionate share of pollution, environmental hazards, and social and economic stressors. Multiple exposures to chemical and non-chemical stressors collectively increase the risk of harm, combined with synergistic effects with other health stressors such as limited access to quality health care.[4,5] EPA's risk evaluations need to fully account for these factors and its problem formulations should explain how it intends to do so.

In regard to greater susceptibility, the following are well-known factors that increase biologic sensitivity or reduce resilience to exposures,[6,7] and should be considered consistently for all 10 chemicals to identify susceptible subpopulations:

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[3] EPA's final risk evaluation rule, in contrast to its proposal, would permit the Agency to select which conditions of use to include in risk evaluation scopes as opposed to including all such uses. 82 Fed. Reg. 33,726 (July 20, 2017). Our groups argued in their comments on the proposal that the law required the Agency to address all conditions of use in its risk evaluations, as was recognized in the Agency's original proposal. Along with several other groups, we are challenging EPA's contrary interpretation in its petition for judicial review of the risk evaluation rule. Regardless of the outcome of this challenge, we believe that EPA has no basis to narrow the risk evaluation to exclude conditions of use once they have been included in its scope.

[4] Morello-Frosch R, Zuk M, Jerrett M, Shamasunder B, Kyle AD. Understanding the cumulative impacts of inequalities in environmental health: Implications for policy. Health Aff. 2011;30(5):879–87.

[5] Vesterinen HM, Morello-Frosch R, Sen S, Zeise L, Woodruff TJ. Cumulative effects of prenatal-exposure to exogenous chemicals and psychosocial stress on fetal growth: Systematic-review of the human and animal evidence. Meliker J, editor. PLoS One. 2017 Jul 12;12(7):e0176331.

[6] Morello-Frosch R, Zuk M, Jerrett M, Shamasunder B, Kyle AD. Understanding the cumulative impacts of inequalities in environmental health: Implications for policy. Health Aff. 2011;30(5):879–87.

Intrinsic/ endogenous factors

- Genetic polymorphisms/ genetics/ genetic makeup
- Health status/ nutritional status/ disease status/ pre-existing conditions
- Prenatal life stage
- Age

Extrinsic factors

- Multiple exposures/ co-exposures
- Race/ ethnicity
- Socioeconomic status (SES)

For example, the prenatal life stage is the most sensitive to developmental and reproductive toxicants, and women of childbearing age should be considered as a susceptible subpopulation for any chemical with such hazards. However, women of reproductive age are not identified as a potential susceptible subpopulation in the scoping documents for pigment violet 29, TCE, NMP, PERC, or HBCD, even though EPA will consider reproductive and developmental toxicity hazards for these chemicals. This omission should be corrected during problem formulation.

III. PROBLEM FORMULATION MUST DESCRIBE EPA'S STRATEGIES FOR ASSESSING RISKS FROM AGGREGATE AND CUMULATIVE EXPOSURES

Problem formulation should also address more fully how EPA intends to address the risks resulting from cumulative and aggregate exposures to each of the 10 chemicals. The scoping documents provide minimal discussion of this essential aspect of risk evaluation design.

Section 6(b)(4)(F)(ii) requires risk evaluations to describe whether aggregate or sentinel exposures to a chemical were considered and the basis for that consideration. To properly apply either or both of these approaches in a risk evaluation, EPA must determine in advance what methodology it will employ and then incorporate it in the risk evaluation design in sufficient detail to describe the key data sources it will use to assess exposure and how they will be used. The scoping documents fail to do this. EPA should remedy this gap in problem formulation.

We believe aggregate exposure assessment will be required for all of the 10 chemicals.[8] The focus of the new law is on determining risk based on all relevant pathways and sources of exposure for the general population and vulnerable subpopulations throughout a chemical's life cycle. Thus, under section 6(b)(4)(F)(i), EPA must "integrate and assess available information on hazards and exposures for *the conditions of use* of the chemical substance" and, under section 6(b)(4)(F)(iv), must "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under *the conditions of use* of the chemical substance." This emphasis on integrating risk and exposure factors across a chemical's conditions of use necessarily requires the Agency to identify all sources of exposure that may affect the general population or specific subpopulations and to determine the overall levels, frequency

[7] National Research Council. Science and Decisions: Advancing Risk Assessment. Washington, D.C.: National Academies Press; 2009.

[8] When analyzing aggregate exposures, "sentinel exposure" may be considered simultaneously, where appropriate. However, these are not mutually exclusive and EPA should not incorporate sentinel to the exclusion of aggregate.

and duration of exposures by each population or subpopulation resulting from this combination of pathways.[9]

EPA has applied the tools of "aggregate exposure assessment" successfully in several programs. For example, the 1996 Food Quality Protection Act (FQPA) directs EPA to examine aggregate exposures when issuing or renewing tolerances for pesticides in food and EPA has longstanding guidance for doing aggregate risk and exposure assessments to meet this requirement.[10]

During problem formulation, EPA should develop a roadmap for each of the 10 chemicals showing what steps it is taking to gather the necessary information for aggregate exposure assessment and how it will calculate or estimate the combined exposures resulting from multiple pathways or uses for the general population and potentially exposed or susceptible subpopulations.

Problem formulations should also address whether and how EPA will use "cumulative risk" methodologies for the first 10 risk evaluations. This, too, is an area that EPA has addressed in several guidance documents.[11] The Agency defines "cumulative risk" as "the combined risks from aggregate exposures (i.e., multiple route exposures) to multiple agents or stressors" and has explained that:

> "In cumulative risk assessments that examine risks posed by multiple chemicals, exposure assessments evaluate a population's chemical exposures through multiple routes of exposure over time. Such assessments may encompass multiple exposure timeframes in which the timing and intensity of exposures to different chemicals are examined relative to each other. It is also important to determine whether the exposures to multiple chemicals can lead to toxicokinetic interactions or toxicodynamic interactions. In addition to providing information about multiple chemical exposures in the general population, these exposure assessments identify potentially susceptible or vulnerable subpopulations in the study area and potentially unique pathways of exposure in those subpopulations."[12]

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[9] Exposures from TSCA-exempt uses such as personal care products or biocides should also be included in scoping documents and risk evaluations because of the need to account for their contribution to aggregate risk, even though regulatory authority over these products is not available under TSCA but derives from other laws administered by EPA or agencies such as FDA. This is now standard practice in implementing the Food Quality Protection Act (FQPA). The scoping documents contain limited and incomplete information on exposures to the listed chemicals from non-TSCA uses.

[10] https://www.epa.gov/sites/production/files/2015-07/documents/aggregate.pdf

[11] E.g., *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity.* U.S. Environmental Protection Agency, Office of Pesticide Programs, Washington, DC. (2002) Available at http://www.epa.gov/oppfead1/trac/science/cumulative_guidance.pdf; *Framework for Cumulative Risk Assessment,* U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Washington, DC. EPA/600/P-02/001F (2004). Available at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=54944.

[12] EPA National Center for Environmental Assessment, *Concepts, Methods and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures and Effects: A Resource Document,* at xxviii (August 2007).

The importance of examining risks posed by multiple chemicals with overlapping pathways of exposure and common adverse health effects was also underscored by the National Academy of Sciences (NAS) in its Phthalates and Cumulative Risk report.[13]

We recommend that, in its problem formulations, EPA should commit to perform cumulative risk assessments whenever a population or subpopulation exposed to the subject chemical is also exposed to other chemicals that have similar health effects. In this situation, total risk to the relevant population or subpopulation will be a function not just of exposure to the subject chemical in isolation but of combined exposure to that chemical and other chemicals which have additive or synergistic health effects.

A compelling case for examining cumulative risks will exist where EPA is in parallel conducting risk evaluations on multiple chemicals within a class that have similar chemical structures, conditions of use and adverse health effects. An example of such a grouping is the four solvents (TCE, PERC, MC and NMP) among the initial 10 chemicals: not only is it likely that workers and consumers are exposed to all or some of these solvents simultaneously but their common hazards (i.e. neurotoxicity, reproductive toxicity) are likely to magnify the risks of such concurrent exposures. The problem formulations for these four chemicals should recognize the need to examine the cumulative risks they present and describe how EPA will evaluate cumulative risk scenarios.

IV. ONGOING USE AND DISPOSAL OF CHEMICAL PRODUCTS THAT ARE NO LONGER BEING MANUFACTURED FALL WITHIN THE TSCA DEFINITION OF "CONDITIONS OF USE" AND MUST BE ASSESSED IN RISK EVALUATIONS

Several of the 10 chemicals – asbestos, perchloroethylene (PERC), TCE, MC, carbon tetrachloride (CTC) and hexabromocyclododecane (HBCD) – contribute to ongoing exposure and risk as a result of historical manufacturing and processing activities that have been discontinued. In many cases, the current and foreseeable risks associated with these activities are significant. Nonetheless, the scoping documents provide limited information about these risk and exposure scenarios and take the position that they are outside the scope of risk evaluations except possibly as a source of information about aggregate exposure. Each scoping document contains this statement:

> "EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. For instance, the conditions of use for purposes of section 6 might reasonably include the use of a chemical substance in insulation where the manufacture, processing or distribution in commerce for that use is prospective or on-going, but would not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical

[13] National Research Council. Committee on the Health Risks of Phthalates, Board on Environmental Studies and Toxicology, Division on Earth and Life Studies. 2008. Phthalates and cumulative risk assessment: the task ahead. Washington, D.C.: National Academies Press.

substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses."[14]

We believe that EPA is incorrectly interpreting the provisions of LCSA. The definition of "conditions of use" in section 3(4) covers the "circumstances . . . under which a chemical substance is . . . known or reasonably foreseen to be . . . used or disposed of." Where a chemical is performing an ongoing *in situ* function as a result of previous manufacturing and processing activity, that function comprises a current "use" of the chemical that is "known" to be occurring.

For example, although asbestos may no longer be sold as insulation, the asbestos insulation installed in millions of US buildings continues to perform insulating functions and thus is a current ongoing "use" of asbestos. Installed asbestos-containing building materials (ACBMs) represent one of the largest sources of asbestos accessible to the general public in the US, and the largest asbestos-exposed population consists of people who occupy buildings and homes with ACBMs. Maintenance and construction activities involving ACBMs are also frequent and widespread and account for the largest present-day increase in mesothelioma illness and death in the US.[15]

Similarly, the Healthy Building Network estimates there are 66-132 million pounds (30,000-60,000 metric tons) of HBCD in insulation in existing buildings.[16] These ongoing insulation uses are and will continue to be critical sources of ongoing exposures. HBCD is also present in cars and furniture as a flame retardant and its use in these long-lived consumer articles will contribute to ongoing exposures for years to come.[17]

Equally important, the disposal of building materials or consumer products containing asbestos or HBCD is an ongoing occurrence as buildings are torn down or remodeled and cars and furniture are replaced. Thus, the resulting releases into the environment and communities comprise a "circumstance . . . under which [these chemicals] are . . . known or reasonably foreseen to be . . . disposed of." As "conditions of use" within the TSCA definition, these activities and the risks they present are likewise required to be addressed in risk evaluations under section 6(b). For both chemicals, the immediate and long-term exposures associated with disposal of *in situ* building materials and products are likely to be widespread and significant well into the future.

To exclude from risk evaluations ongoing and future exposures from *in situ* uses of discontinued products would create a sizable gap in the life-cycle assessments of risk that Congress directed EPA to conduct under the new law. This would deprive the public, scientists and regulators of a comprehensive

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[14] EPA, *Scope of the Risk Evaluation for Asbestos*, June 2017, at 8.

[15] US CDC study, "Malignant Mesothelioma Mortality – United States 1999 to 2005."

[16] Safer Chemicals, Healthy Families et al. Comments to the U.S. Environmental Protection Agency (EPA) on the Scope of its Risk Evaluation for the TSCA Work Plan Chemicals: CYCLIC ALIPHATIC BROMIDE CLUSTER or HEXABROMOCYCLODODECANE (HBCD). March 15, 2017. https://healthybuilding.net/uploads/files/saferchemicals-hbcd.pdf

[17] For chemicals like TCE and PERC, the uses that contributed to widespread contamination of groundwater and drinking water may in fact be uses for which these chemicals are still being sold, requiring EPA to include them in its risk evaluations even under its narrow interpretation of the law.

picture of one of the largest sources of continuing and future risk. One consequence would be that EPA would lack the scientific basis to ban resumption of the sale and distribution of discontinued products containing asbestos, HBCD and similar chemicals despite the unreasonable risks that they present. In addition, decision-makers would be unable to reduce ongoing exposures and impose safeguards against unsafe disposal because they would lack a meaningful risk evaluation to inform these actions. Just as TSCA provides authority to evaluate the risks associated with ongoing exposures from discontinued activities, so it gives EPA the authority under section 6(a) to reduce these risks, yet the Agency would be stymied by the absence of a risk evaluation that provides a basis for such regulation.[18]

In short, EPA must characterize and assess ongoing exposures from the use and disposal of discontinued products and determine the risks they present as part of its risk evaluations on the initial 10 chemicals. The scoping documents provide virtually no discussion of these sources of exposure to the 10 chemicals. Nothing in the law allows EPA to exclude these risks from its evaluations. EPA must correct this omission during problem formulation.

V. OZONE DEPLETION AND GLOBAL WARMING POTENTIAL POSE ENVIRONMENTAL AND HEALTH RISKS THAT FALL WITHIN THE SCOPE OF TSCA RISK EVALUATIONS

In earlier submissions, SCHF and its members highlighted data showing the high ozone depleting potential of MC, CTC and 1-Bromopropane (1-BP).[19] The scoping documents do not address these properties of the three chemicals. Nor do they examine the global warming potential (GWP) of any of the 10 chemicals. These omissions conflict with the express purpose of risk evaluations under section 6(b)(4)(A): to "determine whether a chemical substance presents an unreasonable risk of injury to health *or the environment"* (emphasis added). They also fail to meet the Agency's obligation under section 6(b)(4)(F)(i) to "integrate and assess information . . . that is relevant to specific risks of injury to health *or the environment"* (emphasis added). Ozone depletion and global warming potential clearly pose risks to the environment and they are also recognized risk factors for human health.[20,21] Nothing in the law allows EPA to exclude these risks from its evaluations.

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[18] For some chemicals like lead and asbestos, other laws administered by EPA address handling and disposal of *in situ* materials. The Agency may be able to refer the findings of its risk evaluations to the programs implementing these laws under TSCA section 9(b) in lieu of further regulation under section 6. However, there are no existing laws that address ongoing exposure from use and disposal of discontinued products containing HBCD, perfluorinated chemicals and other substances and therefore the availability of the protections afforded under section 6 of TSCA may be critical to addressing their risks.

[19] See Comments of Safer Chemicals Healthy Families on Risk Evaluation Scoping Documents for Ten Chemical Substances under the Toxic Substances Control Act, March 15, 2017.

[20] The human health risks of ozone depletion are well recognized by the Agency and documented, at least in part, on EPA's webpage, "Health and Environmental Effects of Ozone Layer Depletion:" "Ozone layer depletion increases the amount of UVB that reaches the Earth's surface. Laboratory and epidemiological studies demonstrate that UVB causes non-melanoma skin cancer and plays a major role in malignant melanoma development. In addition, UVB has been linked to the development of cataracts, a clouding of the eye's lens." https://www.epa.gov/ozone-layer-protection/health-and-environmental-effects-ozone-layer-depletion (Accessed 9-18-17)

[21] The human health risks of global warming were well recognized and documented, at least in part, by the agency prior to the arrival of Administrator Pruitt, as outlined in the legacy pages at: https://19january2017snapshot.epa.gov/climate-impacts/climate-impacts-human-health_.html While that page is being updated, "...to reflect EPA's priorities under the leadership of President Trump and Administrator Pruitt," the Agency still notes, "Climate change is having direct and indirect impacts on the health of people. More extreme

The EPA Office of Air and Radiation (OAR) has considerable expertise in both ozone depletion and global warming and has assessed some (but not all) of the 10 chemicals from the perspective of these concerns. OAR can help OCSPP draw on this prior work for its TSCA risk evaluations and perform new assessments for those chemicals whose ozone depletion and global warming impacts have not previously been examined. By addressing these impacts in TSCA risk evaluations, EPA will fulfill the law's goal of providing a comprehensive picture of environmental and health risks across the chemical's life cycle. In particular cases, it may also highlight contributors to ozone depletion and global warming that have been overlooked and may warrant restriction. Whether these impacts can be adequately addressed under the Clean Air Act (CAA) or under TSCA need not be determined in the risk evaluation itself and can be deferred to the later evaluation of risk management options under section 6(a).

VI. EPA RISK EVALUATIONS SHOULD NOT REASSESS USES OF TCE, MC AND NMP THAT WERE FULLY ASSESSED IN ITS PROPOSED SECTION 6(a) RULES

EPA has proposed to ban certain uses of TCE, MC and NMP under section 6(a) of amended TSCA.[22] As the basis for these proposed rules, EPA conducted comprehensive exposure and risk assessments on the targeted uses of the three chemicals. These assessments were subject to public comment and peer review both during their development and again as part of the rulemaking process.

In its scoping documents for the three chemicals, EPA indicates that it intends to rely on the completed assessments and will not "reassess" the targeted uses.[23] We strongly agree with this approach. It would be counterproductive for the Agency reopen these assessments for yet another round of public input and to redo the extensive analysis they contain simply so industry commenters can have another bite at the apple on findings they dislike. Moreover, we believe that the next step in the rulemakings is for EPA to issue final rules as quickly as possible. These rules, once issued, should close the book on the targeted uses and enable EPA to focus its risk evaluations on uses that have not yet been assessed. In its more comprehensive risk evaluations, however, EPA should incorporate its earlier assessments so that the exposures they describe can be accounted for in determining aggregate exposure to the three chemicals.

VII. EPA SHOULD NOT REVISIT DEFINITIVE FINDINGS IN IRIS ASSESSMENTS, WHICH REPRESENT THE AGENCY'S AUTHORITATIVE PEER-REVIEWED DETERMINATIONS OF THE HEALTH EFFECTS OF CHEMICALS

Five of the 10 chemicals – TCE, MC, CTC, PERC and 1,4-dioxane – have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect

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weather events, heat waves, spread of infectious diseases and detrimental impacts on air and water quality are having impacts on our health." https://www.epa.gov/climate-research/human-health-and-climate-change-research (accessed 9-18-17).

[22] Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing under TSCA Section 6(a), 82 Fed. Reg. 7432 (Jan. 19, 2017); Trichloroethylene; Regulation of Certain Uses under TSCA § 6(a), 81 Fed. Reg. 91592 (Dec. 16, 2016) and Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses under TSCA Section 6(a), 82 Fed. Reg. 7464 (Jan. 19, 2017).

[23] See, e.g., EPA. *Scope of the Risk Evaluation for Trichloroethylene,* June 2017, at 33.

years of work by EPA scientists, multiple rounds of public comment, inter and intra-agency consultation, and extensive peer review, often by the Agency's independent Science Advisory Board (SAB) or the National Academy of Sciences (NAS).

Where EPA is conducting a TSCA risk evaluation of a chemical that has already been assessed under IRIS, the conclusions of the IRIS assessment should be presumed to be applicable to the TSCA evaluation as a definitive statement by the Agency of the best available science. To revisit IRIS findings would be inefficient and resource-intensive at a time when the Agency is struggling with workforce and budget reductions. It would also make the three-year statutory deadline for completing risk evaluations even more challenging by greatly expanding the scope of EPA's work effort. Most significantly, reopening IRIS findings would prolong scientific uncertainty on issues that have been addressed and resolved through an authoritative, transparent and inclusive EPA process. Like other Agency actions, IRIS assessments often give rise to differences of opinion and some stakeholders may be disappointed by the outcome. But this does not mean that EPA should reinvent the wheel and provide another bite at the apple on scientific determinations that have been made after thorough deliberation and a robust process.

In sum, the problem formulation documents on the 10 chemicals should make clear that EPA's risk evaluations will rely on previous IRIS assessments in determining health effects that those assessments address.

VIII. IN EVALUATING WORKPLACE RISKS, EPA SHOULD RECOGNIZE THE UNEVEN USE AND EFFECTIVENESS OF ENGINEERING CONTROLS, LABELING AND PERSONAL PROTECTIVE EQUIPMENT IN PREVENTING OCCUPATIONAL EXPOSURE

Several scoping documents indicate that, in its approach to occupational exposure analysis, EPA will "[c]onsider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios."[24] These measures are certainly relevant factors in analyzing occupational exposures. However, it is essential that EPA not presume that they will be effective in preventing exposure in all workplaces and for all employees. In many cases, they may in fact provide limited protection, particularly for short-term poorly trained workers in small shops and workers whose English language skills are challenged.

In its proposed section 6(a) rules for TCE, MC and NMP, EPA explained at some length why label warnings and instructions are not uniformly read, comprehended or followed and thus provide limited protection. This was not a mere opinion on EPA's part but the result of an examination of nearly fifty studies.[25] Based on this review, EPA's conclusions as described in its initial TCE rulemaking were as follows:

> "The Agency determined that warning labels and instructions alone could not mitigate the risks to the extent necessary so that TCE no longer presents the identified unreasonable risks to users. The Agency based this determination on an analysis of 48 relevant studies or meta-analyses, which found that consumers and professionals do not consistently pay attention to

[24] See, for example, US EPA (2017). Scope of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster. Pg. 45

[25] OPPT summarized these studies in a paper entitled *The Effectiveness of Labeling on Hazardous Chemicals and Other Products* (March 2016)(Ref. 33 in rulemaking docket).

labels; consumers and professional users often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies."[26]

In the TCE vapor degreasing proposal, EPA further concluded that comprehension of warnings would be unusually challenging because of the complexity of the information conveyed:

> "EPA found that presenting information about TCE on a label would not adequately address the identified unreasonable risks because the nature of the information the user would need to read, understand, and act upon is extremely complex. It would be challenging to most users to follow or convey the complex product label instructions required to explain how to reduce exposures to the extremely low levels needed to minimize the risk from TCE. Rather than a simple message, the label would need to explain a variety of inter-related factors, including but not limited to the use of local exhaust ventilation, respirators and assigned protection factor for the user and bystanders, and time periods during pregnancy with susceptibility of the developing fetus to acute developmental effects, as well as effects to bystanders. *It is unlikely that label language changes for this use will result in widespread, consistent, and successful adoption of risk reduction measures by users and owners.*[27]

Similarly, EPA cautioned that "there are many documented limitations to successful implementation of respirators", including these well-known problems: [28]

> "Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-face piece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good face piece fit, including those individuals whose beards or sideburns interfere with the face piece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, January 8, 1998). According to OSHA, 'improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health. (63 FR 1189-1190).'"

EPA based these conclusions on expert analyses by OSHA, which has extensive experience with respirators under its workplace standards.

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[26] 81 FR at 91601.
[27] 82 FR 7441 (emphasis added)
[28] 82 FR 7445

The problem formulation documents should explicitly recognize that industrial hygiene controls do not necessarily provide reliable and effective protection from exposure and that the adequacy of these controls needs to be examined on a case-by-case basis in the context of the specific establishments where the chemical is used, the makeup of the worker population in these establishments and the diligence of employers in implementing workplace controls. During problem formulation, EPA should elaborate on how these considerations will be applied for the 10 chemicals.

More generally, when considering occupational exposures, EPA needs to recognize and account for differences in levels of exposure, workplace practices and susceptibility that result in significant gradations in risk, even within a single workplace. In workplaces where chemicals and chemical products are used, exposures typically occur most intensely among a highly exposed subgroup, rather than uniformly across the population of workers. In a vehicle repair shop, for example, chemical-intensive tasks on brakes, engines, and drive-train components are performed by a subset of workers who experience high levels of exposure to aerosolized degreasing solvents, whereas other workers in the same shop who perform diagnostic or electrical work, for example, experience little or no exposure to these solvents. To effectively characterize the "conditions of use" among workers, EPA must account for the levels and duration of exposure—and therefore risk—that occurs within highly exposed subgroups as a consequence of actual workplace conditions, rather than relying on an "average" estimated exposure across a population of workers, based on an assumption of "intended" use.

IX. EPA SHOULD NOT EXCLUDE FROM THE 1,4-DIOXANE EVALUATION ITS PRODUCTION AS A BYPRODUCT OR IMPURITY, WHICH IS A SIGNIFICANT SOURCE OF CONTAMINATION OF WATER SOURCES

The scoping document for 1,4-dioxane takes the unusual approach of precluding any consideration of this substance's manufacture as a byproduct or impurity in EPA's risk evaluation:

> "In the case of 1,4-dioxane, EPA anticipates that production of 1,4-dioxane as a by-product from ethoxylation of other chemicals and presence as a contaminant in industrial, commercial and consumer products will be excluded from the scope of the risk evaluation. These 1,4-dioxane activities will be considered in the scope of the risk evaluation for ethoxylated chemicals. EPA believes its regulatory tools under TSCA section 6(a) are better suited to addressing any unreasonable risks that might arise from these activities through regulation of the activities that generate 1,4-dioxane as an impurity or cause it to be present as a contaminant than they are to addressing them through direct regulation of 1,4-dioxane"[29]

This is a deeply flawed approach that will weaken the 1,4-dioxane risk evaluation and result in inadequate risk reduction during any subsequent rulemaking under section 6(a).

1,4-dioxane is a probable carcinogen that has contaminated drinking water and groundwater in multiple parts of the country, eliciting expressions of concern from many public officials and communities. A recent analysis of data from EPA-mandated monitoring indicates that water supplies for more than 7

[29] Scope of the Risk Evaluation for 1,4-Dioxane, at 8 (June 2017)

million Americans in 27 states contain 1,4-dioxane at levels above those that EPA and other agencies believe present an acceptable cancer risk.[30]

1,4-dioxane's presence in drinking water and groundwater is linked to several pathways of release into the environment. In addition to its manufacture as a chemical product, 1,4-dioxane is a byproduct of plastic production and other chemical manufacturing processes utilizing ethoxylation. Due to its production as a byproduct, it is present as an impurity in several industrial, commercial and consumer products. 1,4-dioxane often is found in the wastewater discharged by industrial facilities and POTWs. Its presence in wastewater is likely attributable not only to intentional production and use activities but to the use and disposal of products in which it is present as an impurity.

If 1,4-dioxane's manufacture as a byproduct and presence in products and waste streams as an impurity are excluded from EPA's risk evaluation, it will have no basis for accounting for these sources of environmental release and will be unable to characterize their contribution to levels of the chemical found in drinking water, surface water and ground water. This will make its assessment of the extent and causes of water contamination incomplete and undermine its ability to conduct an informed evaluation of the options for reducing contamination and risk. Any action it later decides to take under section 6 will thus be based on inadequate information and analysis and, as a result, may be ineffective and under-protective.

Manufacture as a byproduct is plainly within the definition of "conditions of use" in section 3(4) of TSCA. There is no basis in this provision or other parts of the law for differentiating between manufacture as a byproduct and purposeful production and including one in a risk evaluation but excluding the other. And in this instance, there's no evidence (and EPA does not claim) that exposure to and release of 1,4-dioxane as a byproduct and impurity are inconsequential from a risk standpoint.[31]

While EPA suggests that it might be more efficient or effective to address byproduct production of 1,4-dioxane in a separate section 6(a) rulemaking for ethoxylated chemicals, this seems far-fetched. If EPA assesses the contribution of these chemicals to 1,4-dioxane water contamination in the current risk evaluation, it will have a sound basis to regulate their production and use under section 6(a) if they are found to present an unreasonable risk of injury.[32] Otherwise, there is no telling when EPA might mitigate water contamination resulting from byproduct production of 1,4-dioxane production. Thus far, EPA has offered no indication when, if ever, it will make a high-priority designation for ethoxylated chemicals and assess their contribution to the presence of 1,4-dioxane in the environment.

We recommend that during problem formulation, EPA add 1,4-dioxane production as a byproduct and impurity to the scope of its risk evaluation.

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[30] Environmental Working Group, HIDDEN CARCINOGEN TAINTS TAP WATER, CONSUMER PRODUCTS NATIONWIDE (September 2017).

[31] Under our interpretation of section 6(b), EPA could not exclude a condition of use from the risk evaluation scope based on low risk in any event.

[32] Section 6(a) does not limit EPA to regulating purposeful production of a chemical subject to a risk evaluation. It can regulate production by other means so long as it has been assessed in that evaluation and found to present an unreasonable risk.

X. BASED ON THE GENERAL PRINCIPLES OUTLINED ABOVE AND OTHER GAPS IN ITS SCOPING DOCUMENTS, EPA SHOULD AUGMENT THESE DOCUMENTS IN SEVERAL SPECIFIC RESPECTS DURING PROBLEM FORMULATION

Applying the general approaches outlined in these comments and in light of several omissions we identified in individual scoping documents, we recommend that EPA bolster those documents during problem formulation as follows:

1-Bromopropane (nPB)

- In our initial comments to EPA, we specifically identified nPB as being imported by companies whose primary business is supplying the cosmetics industry.[33] While the EPA has noted that authorities such as the State of California have included nPB on lists of chemicals banned in cosmetics, the potential for nPB directly or indirectly (through residues remaining from cleaning manufacturing equipment) to be present in cosmetic products is not addressed as a potential use for further assessment.
- As discussed in detail in Part V of these comments, EPA failed to address the ozone depletion potential of nPB.
- While the scoping document includes references to those exposed to nPB from use of the chemical in consumer products, as well as those co-located with dry cleaning facilities utilizing the chemical, it does not clearly identify people who may be further exposed from chemical residuals, such as those wearing clothing cleaned with nPB or their children. This pathway is not discussed, even though the scoping document for PERC includes it from the similar use of PERC in dry cleaning.

Asbestos

- EPA's scoping document claims that public comments were not received on various imported asbestos containing products available in the United States: "Products available from several online retailers and distributers include brake blocks, aftermarket friction products, roof and non-roof coatings, and gaskets, most of which are imported. No public comments were received regarding these uses." However, we submitted detailed comments highlighting all of these items and more, including other building products. [34]
- EPA's failure to include a lengthy list of legacy uses, as further discussed in Part IV of these comments, is especially problematic for asbestos which was extensively sold and distributed and remains widely present and in use in our buildings and cities.
- The recycling of legacy materials, notably asphalt shingles containing asbestos, is a unique and ongoing use of the substance, and in particular is worthy of additional consideration by the EPA, as discussed in our initial comments.[35]

[33] EPA-HQ-OPPT-2016-0741-0027 at PDF Pages 25, 27, 31.
[34] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 19, 25-27
[35] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 21-22

- There is evidence that asbestos has been present in significant levels in some talc products as the result of colocation of asbestos and talc deposits, as we discussed in our initial comments.[36] This use and ongoing exposure are not addressed in the scoping document.

- The scoping document fails to look at the risks of exposure to those who are upstream to the process of utilizing asbestos in chlor-alkali processing. This would include miners and packaging workers (who, while likely abroad, are still being exposed as a result of the substance's uses in the US considered by the EPA), as well as transportation workers, first responders, and community members who may be exposed in the shipment and transfer of asbestos to the chlor-alkali facilities.

- The absence in the scoping document of total import volumes for asbestos is troubling because it deprives the public of an understanding of the aggregate quantities of asbestos present in the US. In fact, the Asbestos Disease Awareness Organization, along with the Environmental Working Group, released a statement on September 19 that, based on data from the Department of Commerce and US International Trade Commission, 705 metric tons of raw asbestos were imported in 2016, compared to 343 metric tons in 2015. This significant increase in imports is important information that should be given prominence in the problem formulation document for asbestos.

Carbon Tetrachloride (CTC)

- As discussed in detail in Part V of these comments, EPA failed to address the ozone depletion potential and global warming potential of CTC in its scoping document. This is particularly problematic for CTC, as its use as a feedstock or intermediary was exempted from the Montreal Protocol on the false assumption that CTC production would be phased out. In actuality, CTC production is poised for an increase due to its use in HFO manufacture, as we discussed on our initial comments.[37]

- As discussed in detail in Part III of these comments, EPA failed to describe with any specificity how it will look at aggregate and cumulative exposures. In the CTC scoping document, EPA seems to specifically discredit the need for this consideration. The Agency highlights the fact that some individuals may be exposed to CTC through vapor intrusion of ground sources of CTC into their home, but then states that, ". . . this route is not likely to be significant given the agency's identified conditions of use . . ." Clearly, whether the CTC inhaled by a resident is from the vapor intrusion or from an adhesive product, they face potential health risks from it. The Agency must consider all uses and sources of exposure in the risk evaluation in order to accurately assess the human health risk and fulfill its statutory obligations.

Cyclic Aliphatic Bromides Cluster (HBCD)

- As detailed in Part IV of these comments, EPA must not exclude the ongoing use and disposal from past introduction of HBCD in a variety of products. Significant exposures will continue to occur as products incorporating HBCD move through their lifecycle, and these exposures must be considered in the risk evaluation.

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[36] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 18-19

[37] EPA-HQ-OPPT-2016-0733-0023 at PDF pages 4-5, 19

N-Methylpyrrolidone (NMP)

- As we documented in our initial comments to the EPA, NMP has been used in the manufacturing of coating for the insides of aluminum spray cans.[38] Even products not including deliberate addition of NMP may therefore be contaminated with NMP, and this exposure pathway should be considered by the Agency.

- As detailed in Part II of these comments, EPA failed to provide specifics on susceptible subpopulations. While the Agency acknowledges that reproductive effects are to be assessed, considering the well-documented reproductive toxicity of NMP, the Agency needs to better detail how the risks to women of childbearing age will be addressed.

Methylene Chloride (MC)

- While the scoping document includes a use categorization for "other consumer products" including novelty "Drinking Bird" items, we identified an additional item,[39] a "Novelty Christmas Bubbling Night Light" labeled as containing MC but not previously included in EPA's "Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Methylene Chloride." These consumer-oriented uses that are attractive to children illustrate the need to be comprehensive in the determination of "reasonably foreseeable" uses.

XI. EPA MAY NOT PREJUDGE THE ABSENCE OF ADVERSE EFFECTS FOR PARTICULAR END-POINTS AT THE SCOPING STAGE AND SHOULD DEFER SUCH CONCLUSIONS UNTIL THE SYSTEMATIC REVIEW STAGE OF ITS RISK EVALUATION

In some scoping documents, EPA has decided that the subject chemical does not raise concerns for particular endpoints and, therefore, it will not address these end-points in its risk evaluation. Examples are given in the table below where EPA concludes that HBCD, NMP and pigment violet 29 are not genotoxic:

Chemical	Example Text from EPA Scoping Document
HBCD	"Available data suggest that HBCD is not genotoxic. Existing assessments have also concluded, based on genotoxicity information and a limited lifetime study, that HBCD is not carcinogenic (NICNAS, 2012; EINECS, 2008; TemaNord, 2008; OECD, 2007). Unless new information indicates otherwise, EPA does not expect to conduct additional in-depth analysis of genotoxicity or cancer hazards in the risk evaluation of HBCD at this time."[40]
NMP	"NMP is not mutagenic, based on results from bacterial and mammalian *in vitro* tests and *in vivo* systems and is not considered to be carcinogenic (RIVM, 2013; OECD, 2007; WHO, 2001). Unless new information indicates otherwise, EPA does not expect to conduct additional in-depth analysis of genotoxicity and cancer hazards in the NMP risk evaluation."[41]

[38] EPA-HQ-OPPT-2016-0743-0031 at PDF page 18
[39] https://www.amazon.com/Bubble-Nightlight-Novelty-Christmas-Bubbling/dp/B00PV61HXC/
[40] EPA, *Scope of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster, June 2017, at.* 36
[41] EPA, *Scope of the Risk Evaluation for N-Methylpyrrolidone,* June 2017, *at* 36

Pigment violet 29	"Testing for carcinogenicity of Pigment Violet 29 has not been conducted. However, negative genotoxicity results, structure-activity considerations and the expectation of negligible absorption and uptake of Pigment Violet 29 (based on very low solubility), indicate carcinogenicity of Pigment Violet 29 is unlikely. Unless new information indicates otherwise, EPA does not expect to conduct additional, in-depth analyses of genotoxicity and cancer hazards in the risk evaluation of Pigment Violet 29."[42]

EPA cannot reach such definitive conclusions at the scoping stage. The required course under the law is to proceed with a systematic review of the relevant data (a process that EPA strongly endorses) and withhold any conclusions about particular end-points until this review is complete.

In the case of HBCD, for example, a more thorough review would reveal two recent studies indicating carcinogenic potential. One suggests that HBCD could "enhance progression of prostate cancer by modulating growth and migration of LNCaP prostate cells,"[43] and the other concludes the genotoxicity of HBCD is dose-dependent and related to DNA repair.[44] These new studies are examples of the need for EPA to assure that it has fully considered all the available data through the systematic review process in order to avoid premature and possibly incorrect decisions to drop particular end-points at the scoping stage.

XII. PROBLEM FORMULATIONS SHOULD HIGHLIGHT ASPECTS OF USE AND EXPOSURE WHERE AVAILABLE INFORMATION IS INSUFFICIENT AND REQUEST OR REQUIRE SUBMISSION OF THIS INFORMATION BY INDUSTRY

Our own research on the 10 chemicals and the scoping documents themselves confirm that there are significant gaps in the use and exposure information available to EPA and that they will weaken the quality of EPA's risk evaluations unless filled. Although the timeframe for completing risk evaluations is compressed, there is still a window for augmenting the information-base used to conduct them. To take advantage of this opportunity, EPA should include in each problem formulation document a description of information on use and exposure that is lacking and a request that industry and other interested parties submit or obtain that information as expeditiously as possible.

EPA should also signal its readiness to use its mandatory information collection authorities under TSCA to fill data-gaps where voluntary submissions are not timely or adequate. The LCSA expands these authorities and streamlines the process for exercising them, removing the barriers to information development that hamstrung EPA under the old law. For example, section 4 now authorizes EPA to issue orders where necessary to "perform a risk evaluation." Such orders can be used to require industry to develop new information on the frequency, levels and duration of exposure for a chemical's conditions of use. Alternatively, EPA can use its subpoena authority under section 11 to obtain such information that already exists but has not been provided to EPA. EPA should specify in the problem formulation document its roadmap and timetable for filling data gaps using these authorities.

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[42] EPA, *Scope of the Risk Evaluation for Pigment Violet 29*, June 2017, at 29.

[43] Seung-Hee Kim, et al, 2016. Influence of hexabromocyclododecane and 4-nonylphenol on the regulation of cell growth, apoptosis and migration in prostatic cancer cells. Toxicology in Vitro. 32:240-247. April 2016.

[44] Rui Jing Li, et al. Hexabromocyclododecane-induced Genotoxicity in Cultured Human Breast Cells through DNA Damage. Letter to Editor. Biomedical and Environmental Sciences. 30(4): 296-300.

Where the database available for a risk evaluation is incomplete, it is critically important that EPA not equate the absence of data with the absence of risk. For example, if EPA lacks data to assess a chemical's carcinogenicity, its risk evaluation needs to clearly state that cancer risk has not been addressed, that the chemical may or may not present such a risk, and that this end-point is outside the scope of its evaluation because of the absence of data. EPA should make the same disclaimers for conditions of use that cannot be adequately characterized, even by using default assumptions or extrapolation methods, because basic information about the nature of the use and scope and extent of exposure is unavailable.

XIII. EPA NEEDS TO LIMIT REDACTION FROM SCOPING AND PROBLEM FORMULATION DOCUMENTS OF CRITICAL INFORMATION CLAIMED CBI SO THAT TRANSPARENCY AND PUBLIC PARTICIPATION IN THE RISK EVALUATION PROCESS ARE NOT IMPAIRED

The scoping documents omit critical exposure and use information that has been claimed as confidential business information (CBI) that must be withheld from disclosure under TSCA. In some cases, the information is as basic as the total volume of the chemical manufactured and imported in the US. For example, the scoping documents fail to provide total manufacture/import volumes for asbestos, HBCD and pigment violet 29. Not only is this information obtainable in the public domain but it is fundamental to public understanding of the risks posed by these chemicals and, therefore, to informed public participation in the risk evaluation process.[45]

During problem formulation, EPA should make a concerted effort to limit the redaction of CBI-claimed production, use and exposure data that are essential for the transparency of the risk evaluation process. Several tools can be used for this purpose.

First, section 14(b)(3) of TSCA declares that "information not protected from disclosure" includes:

> "any general information describing the manufacturing volumes, expressed as specific aggregated volumes or . . . expressed in ranges."
>
> "a general description of a process used in the manufacture or processing and industrial, commercial or consumer functions and uses of a chemical, substance, mixture or article containing a chemical substance or mixture . . ."

This provision compels the disclosure of much of the information in scoping documents claimed CBI.

Alternatively, section 14(d)(7) provides that the Administrator may disclose information otherwise warranting CBI protection if he or she "determines that disclosure is relevant in a proceeding under this Act." The risk evaluations that EPA is conducting on the 10 chemicals under section 6(b)(2)(A) of TSCA represent a "proceeding" under TSCA. Information submitted by industry on the 10 chemicals is plainly "relevant" to these evaluations because it will inform how EPA assesses exposures and related risks

[45] For asbestos, SCHF and Environmental Health Strategy Center were able to use US government data accessible through the Panjiva database to determine annual asbestos imports over an extended period. As noted above, a more recent analysis of import data by the Asbestos Disease Awareness Organization shows that asbestos imports doubled in 2016, a startling finding that should be central to EPA's risk evaluation because of its implications for exposure to asbestos in the US.

associated with manufacture, processing and downstream commercial and consumer use. Thus, EPA can and should decide to disclose all information on the 10 chemicals notwithstanding any CBI claims.

Finally, to the extent these grounds for disclosure do not apply, EPA should use its authority under section 14(f)(1)(C) to require immediate substantiation of CBI claims for information for which "disclosure would be important to assist the Administrator in conducting risk evaluations . . . under section 6." This provision should be applied broadly to accomplish disclosure of all information that would be of value to the public in commenting on risk evaluations.

CONCLUSION

Our groups appreciate the opportunity to comment on the 10 scoping documents and look forward to continued dialogue with the Agency as it develops problem formulation documents and proceeds with risk evaluations on the 10 chemicals.

If you have any questions, please contact SCHF counsel, Bob Sussman, at bobsussman1@comcast.net or 202-716-0118.

Respectfully submitted,

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September 19, 2017

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families on Risk Evaluation Scoping Documents for Ten Chemical Substances under the Toxic Substances Control Act

Submitted via Regulations.gov (September 19, 2017)

1,4-Dioxane. Docket ID No.: EPA-HQ-OPPT-2016-0723.

1-Bromopropane. Docket ID No.: EPA-HQ-OPPT-2016-0741.

Asbestos. Docket ID No.: EPA-HQ-OPPT-2016-0736.

Carbon Tetrachloride. Docket ID No.: EPA-HQ-OPPT-2016-0733.

Cyclic Aliphatic Bromide Cluster (Hexabromocyclododecane or HBCD). Docket ID No.: EPA-HQ-OPPT-2016-0735.

Methylene Chloride. Docket ID No.: EPA-HQ-OPPT-2016-0742.

N-Methylpyrrolidone (NMP). Docket ID No.: EPA-HQ-OPPT-2016-0743.

Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f]diisoquinoline-1,3,8,10(2H,9H)-tetrone). Docket ID No.: EPA-HQ-OPPT-2016-0725.

Trichloroethylene (TCE). Docket ID No.: EPA-HQ-OPPT-2016-0737.

Tetrachloroethylene (also known as Perchloroethylene). Docket ID No.: EPA-HQ-OPPT-2016-0732.

INTRODUCTION AND SUMMARY

Safer Chemicals, Health Families (SCHF), Earthjustice, Natural Resources Defense Council (NRDC), Environmental Health Strategy Center, Toxic-Free Future and Asbestos Disease Awareness Organization (ADAO) submit these comments on the scoping documents developed by the Environmental Protection Agency (EPA) on the initial 10 chemicals selected for risk evaluations under the newly enacted Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). These organizations are committed to enhancing the safety of chemicals used in homes, workplaces and products and strongly support effective and health-protective implementation of the LCSA.

Through LCSA, Congress amended the Toxic Substances Control Act (TSCA) to establish a new framework for conducting timely, comprehensive and science-based risk evaluations for chemicals of concern. The law provides that EPA's evaluations must be strictly risk-based and must result in a definitive determination of whether the evaluated substance as a whole presents an unreasonable risk of injury to health and the environment across its life cycle, without regard to cost and other non-risk factors.

Congress wanted EPA to launch the risk evaluation process expeditiously. Accordingly, in section 6(b)(2)(A) of TSCA, it directed EPA to assure that evaluations are initiated within six months of the law's enactment on 10 substances drawn from the 2014 TSCA Workplan list. EPA designated these 10 substances on December 19, 2016,[1] and following a public meeting and comment period, released draft scoping documents on June 22. Soon thereafter, EPA announced that it was developing problem formulation documents on the 10 chemicals and would release them for further comment by the end of the year. It also requested comments on the scoping documents in order to inform its approach to problem formulation.[2]

These comments address general issues common to the 10 chemicals as well as several chemical-specific issues. We are submitting our comments to all ten of the EPA dockets. The comments build on earlier submissions by these groups, including our March 15 comments on the scoping process and our July 24 letter to the Agency providing initial reactions to the 10 scoping documents. We have coordinated with a number of other public health and scientific organizations in developing comments on the scoping documents and generally support their recommendations.

The main messages and key recommendations in our comments are as follows:

- Problem formulation can fill gaps in scoping documents and enhance their depth of analysis but cannot be used to remove uses, exposures and hazards from the risk evaluation scope
- EPA should use problem formulation to provide more detail on the potentially exposed and susceptible subpopulations it will consider and how risks to these subpopulations will be determined
- Problem formulations should also describe EPA's strategies for assessing risks from aggregate and cumulative exposures
- Ongoing use and disposal of chemical products that are no longer being manufactured fall within the TSCA definition of "conditions of use" and must be included in problem formulations and assessed in risk evaluations
- Chemicals with ozone depletion and global warming potential pose environmental and health risks that fall within the scope of TSCA risk evaluations
- EPA risk evaluations should not reassess uses of trichloroethylene (TCE), methylene chloride (MC) and N-Methylpyrrolidone (NMP) that were fully assessed in its proposed section 6(a) rules, although these exposure pathways should be included in its determinations of aggregate exposure to these chemicals
- In the course of TSCA risk evaluations, EPA should not revisit definitive findings in IRIS assessments since these assessments represent the Agency's authoritative, peer reviewed determinations on the health effects of the chemicals they address
- In evaluating workplace risks, EPA should recognize and account for the uneven use and effectiveness of engineering controls, labeling and personal protective equipment in preventing occupational exposure and determine risks to workers in situations where these measures are not in place or ineffective
- EPA should not exclude from the 1,4-dioxane evaluation its production as a byproduct or impurity, which is a significant source of contamination of water sources and cancer risk

[1] 81 Federal Register 91927
[2] 82 Fed. Reg. 31,592 (July 7, 2017).

- In order to apply these general principles and fill other gaps in its scoping documents, these documents must be expanded and strengthened in several specific respects during problem formulation
- EPA should not prejudge the absence of adverse effects for particular end-points at the scoping stage but should defer such conclusions until the systematic review phase of its risk evaluation as the law requires
- Problem formulations should highlight aspects of use and exposure where available information is insufficient and request or require submission of this information by industry and other interested parties
- EPA needs to take stronger steps to limit CBI treatment of critical information during the risk evaluation process so that transparency and public participation in that process are not impaired

I. PROBLEM FORMULATION CAN FILL GAPS IN SCOPING DOCUMENTS AND ENHANCE THEIR DEPTH OF ANALYSIS BUT CANNOT BE USED TO REMOVE USES, EXPOSURES AND HAZARDS FROM THE RISK EVALUATION SCOPE

The 10 chemicals undergoing risk evaluations have widespread and substantial exposure and multiple adverse health effects. Comprehensive and health protective assessments of their safety are essential to safeguard communities and vulnerable populations and to set a precedent for strong and effective implementation of the new law. For this reason, our groups made a significant investment in characterizing the use and exposure profiles of several of the 10 chemicals and provided extensive submissions to the Agency to help inform its scoping documents for these chemicals.

The scoping documents represent a considerable amount of work in a short period of time and provide a helpful starting point for the 10 evaluations. However, the July 7 Federal Register notice announcing the availability of the scoping documents acknowledges that the Agency was unable to process all the information gathered during the scoping process and that the scoping documents were not as "refined or specific" as EPA had hoped. We agree with this assessment and believe that the scoping documents contain serious gaps, lack sufficient information on use and exposure, impose questionable limitations on the risk scenarios to be examined and fail to provide a roadmap to key elements of assessment methodology. These shortcomings reduce the utility of the scoping documents in laying the groundwork for well-informed and rigorous risk evaluations.

Given their limitations, we believe that expanding and strengthening the scoping documents through a problem formulation process is appropriate in this instance. However, neither LCSA nor the recently promulgated risk evaluation process rule refers to or authorizes problem formulation. Because it has no basis in the law, we oppose using problem formulation to narrow the scope of risk evaluations by deleting conditions of use, exposure pathways or health or environmental end-points identified in the June scoping documents. Section 6(b)(4)(D) of amended TSCA provides that, "not later than 6 months after the initiation of a risk evaluation," EPA must "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and the potentially exposed or susceptible subpopulations the Administrator expects to consider." EPA met this requirement in its June scoping documents. The law provides no basis for EPA to remove uses, hazards or exposures from a risk

evaluation after its scope has been established in accordance with section 6(b)(4)(D).[3] Since problem formulation is not a recognized step in the risk evaluation process or a substitute for scoping under LCSA, it cannot be used narrow a risk evaluation's scope after-the-fact.

We do support, however, using problem formulation to provide more detail on the conditions of use, potentially exposed and susceptible subpopulations, and exposure pathways that EPA will evaluate as well as further explanation of the methodologies that EPA will use in its analysis of these and other risk assessment elements. This will help better structure the risk evaluations, assure that all relevant information is considered, and characterize more fully the conditions of use to be evaluated – without narrowing the risk evaluation scope.

II. EPA SHOULD USE PROBLEM FORMULATION TO PROVIDE MORE DETAIL ON THE POTENTIALLY EXPOSED AND SUSCEPTIBLE SUBPOPULATIONS IT WILL CONSIDER AND HOW RISKS TO THESE SUBPOPULATIONS WILL BE DETERMINED

One area that would benefit from greater elaboration during problem formulation is the identification of potentially exposed or susceptible subpopulations that require consideration in risk evaluations under TSCA section 6(b)(4)(F). The scoping documents provide nearly identical general "boilerplate" descriptions of such subpopulations. Further particulars on the size, geographic location, demographic characteristics and exposure profile of each subpopulation EPA has identified would provide helpful assurance that the risks to that subpopulation will be characterized with the rigor that TSCA requires.

It is also critical for EPA to spell out the methodology it intends to use to determine the nature and magnitude of the risks that chemicals pose to each subpopulation. Such subpopulations are often comprised of low income and/or people of color and exposed to a disproportionate share of pollution, environmental hazards, and social and economic stressors. Multiple exposures to chemical and non-chemical stressors collectively increase the risk of harm, combined with synergistic effects with other health stressors such as limited access to quality health care.[4,5] EPA's risk evaluations need to fully account for these factors and its problem formulations should explain how it intends to do so.

In regard to greater susceptibility, the following are well-known factors that increase biologic sensitivity or reduce resilience to exposures,[6,7] and should be considered consistently for all 10 chemicals to identify susceptible subpopulations:

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[3] EPA's final risk evaluation rule, in contrast to its proposal, would permit the Agency to select which conditions of use to include in risk evaluation scopes as opposed to including all such uses. 82 Fed. Reg. 33,726 (July 20, 2017). Our groups argued in their comments on the proposal that the law required the Agency to address all conditions of use in its risk evaluations, as was recognized in the Agency's original proposal. Along with several other groups, we are challenging EPA's contrary interpretation in its petition for judicial review of the risk evaluation rule. Regardless of the outcome of this challenge, we believe that EPA has no basis to narrow the risk evaluation to exclude conditions of use once they have been included in its scope.

[4] Morello-Frosch R, Zuk M, Jerrett M, Shamasunder B, Kyle AD. Understanding the cumulative impacts of inequalities in environmental health: Implications for policy. Health Aff. 2011;30(5):879–87.

[5] Vesterinen HM, Morello-Frosch R, Sen S, Zeise L, Woodruff TJ. Cumulative effects of prenatal-exposure to exogenous chemicals and psychosocial stress on fetal growth: Systematic-review of the human and animal evidence. Meliker J, editor. PLoS One. 2017 Jul 12;12(7):e0176331.

[6] Morello-Frosch R, Zuk M, Jerrett M, Shamasunder B, Kyle AD. Understanding the cumulative impacts of inequalities in environmental health: Implications for policy. Health Aff. 2011;30(5):879–87.

Intrinsic/ endogenous factors

- Genetic polymorphisms/ genetics/ genetic makeup
- Health status/ nutritional status/ disease status/ pre-existing conditions
- Prenatal life stage
- Age

Extrinsic factors

- Multiple exposures/ co-exposures
- Race/ ethnicity
- Socioeconomic status (SES)

For example, the prenatal life stage is the most sensitive to developmental and reproductive toxicants, and women of childbearing age should be considered as a susceptible subpopulation for any chemical with such hazards. However, women of reproductive age are not identified as a potential susceptible subpopulation in the scoping documents for pigment violet 29, TCE, NMP, PERC, or HBCD, even though EPA will consider reproductive and developmental toxicity hazards for these chemicals. This omission should be corrected during problem formulation.

III. PROBLEM FORMULATION MUST DESCRIBE EPA'S STRATEGIES FOR ASSESSING RISKS FROM AGGREGATE AND CUMULATIVE EXPOSURES

Problem formulation should also address more fully how EPA intends to address the risks resulting from cumulative and aggregate exposures to each of the 10 chemicals. The scoping documents provide minimal discussion of this essential aspect of risk evaluation design.

Section 6(b)(4)(F)(ii) requires risk evaluations to describe whether aggregate or sentinel exposures to a chemical were considered and the basis for that consideration. To properly apply either or both of these approaches in a risk evaluation, EPA must determine in advance what methodology it will employ and then incorporate it in the risk evaluation design in sufficient detail to describe the key data sources it will use to assess exposure and how they will be used. The scoping documents fail to do this. EPA should remedy this gap in problem formulation.

We believe aggregate exposure assessment will be required for all of the 10 chemicals.[8] The focus of the new law is on determining risk based on all relevant pathways and sources of exposure for the general population and vulnerable subpopulations throughout a chemical's life cycle. Thus, under section 6(b)(4)(F)(i), EPA must "integrate and assess available information on hazards and exposures for *the conditions of use* of the chemical substance" and, under section 6(b)(4)(F)(iv), must "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under *the conditions of use* of the chemical substance." This emphasis on integrating risk and exposure factors across a chemical's conditions of use necessarily requires the Agency to identify all sources of exposure that may affect the general population or specific subpopulations and to determine the overall levels, frequency

[7] National Research Council. Science and Decisions: Advancing Risk Assessment. Washington, D.C.: National Academies Press; 2009.

[8] When analyzing aggregate exposures, "sentinel exposure" may be considered simultaneously, where appropriate. However, these are not mutually exclusive and EPA should not incorporate sentinel to the exclusion of aggregate.

and duration of exposures by each population or subpopulation resulting from this combination of pathways.[9]

EPA has applied the tools of "aggregate exposure assessment" successfully in several programs. For example, the 1996 Food Quality Protection Act (FQPA) directs EPA to examine aggregate exposures when issuing or renewing tolerances for pesticides in food and EPA has longstanding guidance for doing aggregate risk and exposure assessments to meet this requirement.[10]

During problem formulation, EPA should develop a roadmap for each of the 10 chemicals showing what steps it is taking to gather the necessary information for aggregate exposure assessment and how it will calculate or estimate the combined exposures resulting from multiple pathways or uses for the general population and potentially exposed or susceptible subpopulations.

Problem formulations should also address whether and how EPA will use "cumulative risk" methodologies for the first 10 risk evaluations. This, too, is an area that EPA has addressed in several guidance documents.[11] The Agency defines "cumulative risk" as "the combined risks from aggregate exposures (i.e., multiple route exposures) to multiple agents or stressors" and has explained that:

> "In cumulative risk assessments that examine risks posed by multiple chemicals, exposure assessments evaluate a population's chemical exposures through multiple routes of exposure over time. Such assessments may encompass multiple exposure timeframes in which the timing and intensity of exposures to different chemicals are examined relative to each other. It is also important to determine whether the exposures to multiple chemicals can lead to toxicokinetic interactions or toxicodynamic interactions. In addition to providing information about multiple chemical exposures in the general population, these exposure assessments identify potentially susceptible or vulnerable subpopulations in the study area and potentially unique pathways of exposure in those subpopulations."[12]

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[9] Exposures from TSCA-exempt uses such as personal care products or biocides should also be included in scoping documents and risk evaluations because of the need to account for their contribution to aggregate risk, even though regulatory authority over these products is not available under TSCA but derives from other laws administered by EPA or agencies such as FDA. This is now standard practice in implementing the Food Quality Protection Act (FQPA). The scoping documents contain limited and incomplete information on exposures to the listed chemicals from non-TSCA uses.

[10] https://www.epa.gov/sites/production/files/2015-07/documents/aggregate.pdf

[11] E.g., *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity.* U.S. Environmental Protection Agency, Office of Pesticide Programs, Washington, DC. (2002) Available at http://www.epa.gov/oppfead1/trac/science/cumulative_guidance.pdf; *Framework for Cumulative Risk Assessment,* U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Washington, DC. EPA/600/P-02/001F (2004). Available at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=54944.

[12] EPA National Center for Environmental Assessment, *Concepts, Methods and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures and Effects: A Resource Document,* at xxviii (August 2007).

The importance of examining risks posed by multiple chemicals with overlapping pathways of exposure and common adverse health effects was also underscored by the National Academy of Sciences (NAS) in its Phthalates and Cumulative Risk report.[13]

We recommend that, in its problem formulations, EPA should commit to perform cumulative risk assessments whenever a population or subpopulation exposed to the subject chemical is also exposed to other chemicals that have similar health effects. In this situation, total risk to the relevant population or subpopulation will be a function not just of exposure to the subject chemical in isolation but of combined exposure to that chemical and other chemicals which have additive or synergistic health effects.

A compelling case for examining cumulative risks will exist where EPA is in parallel conducting risk evaluations on multiple chemicals within a class that have similar chemical structures, conditions of use and adverse health effects. An example of such a grouping is the four solvents (TCE, PERC, MC and NMP) among the initial 10 chemicals: not only is it likely that workers and consumers are exposed to all or some of these solvents simultaneously but their common hazards (i.e. neurotoxicity, reproductive toxicity) are likely to magnify the risks of such concurrent exposures. The problem formulations for these four chemicals should recognize the need to examine the cumulative risks they present and describe how EPA will evaluate cumulative risk scenarios.

IV. ONGOING USE AND DISPOSAL OF CHEMICAL PRODUCTS THAT ARE NO LONGER BEING MANUFACTURED FALL WITHIN THE TSCA DEFINITION OF "CONDITIONS OF USE" AND MUST BE ASSESSED IN RISK EVALUATIONS

Several of the 10 chemicals – asbestos, perchloroethylene (PERC), TCE, MC, carbon tetrachloride (CTC) and hexabromocyclododecane (HBCD) – contribute to ongoing exposure and risk as a result of historical manufacturing and processing activities that have been discontinued. In many cases, the current and foreseeable risks associated with these activities are significant. Nonetheless, the scoping documents provide limited information about these risk and exposure scenarios and take the position that they are outside the scope of risk evaluations except possibly as a source of information about aggregate exposure. Each scoping document contains this statement:

> "EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. For instance, the conditions of use for purposes of section 6 might reasonably include the use of a chemical substance in insulation where the manufacture, processing or distribution in commerce for that use is prospective or on-going, but would not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical

[13] National Research Council. Committee on the Health Risks of Phthalates, Board on Environmental Studies and Toxicology, Division on Earth and Life Studies. 2008. Phthalates and cumulative risk assessment: the task ahead. Washington, D.C.: National Academies Press.

substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses."[14]

We believe that EPA is incorrectly interpreting the provisions of LCSA. The definition of "conditions of use" in section 3(4) covers the "circumstances . . . under which a chemical substance is . . . known or reasonably foreseen to be . . . used or disposed of." Where a chemical is performing an ongoing *in situ* function as a result of previous manufacturing and processing activity, that function comprises a current "use" of the chemical that is "known" to be occurring.

For example, although asbestos may no longer be sold as insulation, the asbestos insulation installed in millions of US buildings continues to perform insulating functions and thus is a current ongoing "use" of asbestos. Installed asbestos-containing building materials (ACBMs) represent one of the largest sources of asbestos accessible to the general public in the US, and the largest asbestos-exposed population consists of people who occupy buildings and homes with ACBMs. Maintenance and construction activities involving ACBMs are also frequent and widespread and account for the largest present-day increase in mesothelioma illness and death in the US.[15]

Similarly, the Healthy Building Network estimates there are 66-132 million pounds (30,000-60,000 metric tons) of HBCD in insulation in existing buildings.[16] These ongoing insulation uses are and will continue to be critical sources of ongoing exposures. HBCD is also present in cars and furniture as a flame retardant and its use in these long-lived consumer articles will contribute to ongoing exposures for years to come.[17]

Equally important, the disposal of building materials or consumer products containing asbestos or HBCD is an ongoing occurrence as buildings are torn down or remodeled and cars and furniture are replaced. Thus, the resulting releases into the environment and communities comprise a "circumstance . . . under which [these chemicals] are . . . known or reasonably foreseen to be . . . disposed of." As "conditions of use" within the TSCA definition, these activities and the risks they present are likewise required to be addressed in risk evaluations under section 6(b). For both chemicals, the immediate and long-term exposures associated with disposal of *in situ* building materials and products are likely to be widespread and significant well into the future.

To exclude from risk evaluations ongoing and future exposures from *in situ* uses of discontinued products would create a sizable gap in the life-cycle assessments of risk that Congress directed EPA to conduct under the new law. This would deprive the public, scientists and regulators of a comprehensive

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[14] EPA, *Scope of the Risk Evaluation for Asbestos*, June 2017, at 8.

[15] US CDC study, "Malignant Mesothelioma Mortality – United States 1999 to 2005."

[16] Safer Chemicals, Healthy Families et al. Comments to the U.S. Environmental Protection Agency (EPA) on the Scope of its Risk Evaluation for the TSCA Work Plan Chemicals: CYCLIC ALIPHATIC BROMIDE CLUSTER or HEXABROMOCYCLODODECANE (HBCD). March 15, 2017. https://healthybuilding.net/uploads/files/saferchemicals-hbcd.pdf

[17] For chemicals like TCE and PERC, the uses that contributed to widespread contamination of groundwater and drinking water may in fact be uses for which these chemicals are still being sold, requiring EPA to include them in its risk evaluations even under its narrow interpretation of the law.

picture of one of the largest sources of continuing and future risk. One consequence would be that EPA would lack the scientific basis to ban resumption of the sale and distribution of discontinued products containing asbestos, HBCD and similar chemicals despite the unreasonable risks that they present. In addition, decision-makers would be unable to reduce ongoing exposures and impose safeguards against unsafe disposal because they would lack a meaningful risk evaluation to inform these actions. Just as TSCA provides authority to evaluate the risks associated with ongoing exposures from discontinued activities, so it gives EPA the authority under section 6(a) to reduce these risks, yet the Agency would be stymied by the absence of a risk evaluation that provides a basis for such regulation.[18]

In short, EPA must characterize and assess ongoing exposures from the use and disposal of discontinued products and determine the risks they present as part of its risk evaluations on the initial 10 chemicals. The scoping documents provide virtually no discussion of these sources of exposure to the 10 chemicals. Nothing in the law allows EPA to exclude these risks from its evaluations. EPA must correct this omission during problem formulation.

V. OZONE DEPLETION AND GLOBAL WARMING POTENTIAL POSE ENVIRONMENTAL AND HEALTH RISKS THAT FALL WITHIN THE SCOPE OF TSCA RISK EVALUATIONS

In earlier submissions, SCHF and its members highlighted data showing the high ozone depleting potential of MC, CTC and 1-Bromopropane (1-BP).[19] The scoping documents do not address these properties of the three chemicals. Nor do they examine the global warming potential (GWP) of any of the 10 chemicals. These omissions conflict with the express purpose of risk evaluations under section 6(b)(4)(A): to "determine whether a chemical substance presents an unreasonable risk of injury to health *or the environment"* (emphasis added). They also fail to meet the Agency's obligation under section 6(b)(4)(F)(i) to "integrate and assess information . . . that is relevant to specific risks of injury to health *or the environment"* (emphasis added). Ozone depletion and global warming potential clearly pose risks to the environment and they are also recognized risk factors for human health.[20,21] Nothing in the law allows EPA to exclude these risks from its evaluations.

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[18] For some chemicals like lead and asbestos, other laws administered by EPA address handling and disposal of *in situ* materials. The Agency may be able to refer the findings of its risk evaluations to the programs implementing these laws under TSCA section 9(b) in lieu of further regulation under section 6. However, there are no existing laws that address ongoing exposure from use and disposal of discontinued products containing HBCD, perfluorinated chemicals and other substances and therefore the availability of the protections afforded under section 6 of TSCA may be critical to addressing their risks.

[19] See Comments of Safer Chemicals Healthy Families on Risk Evaluation Scoping Documents for Ten Chemical Substances under the Toxic Substances Control Act, March 15, 2017.

[20] The human health risks of ozone depletion are well recognized by the Agency and documented, at least in part, on EPA's webpage, "Health and Environmental Effects of Ozone Layer Depletion:" "Ozone layer depletion increases the amount of UVB that reaches the Earth's surface. Laboratory and epidemiological studies demonstrate that UVB causes non-melanoma skin cancer and plays a major role in malignant melanoma development. In addition, UVB has been linked to the development of cataracts, a clouding of the eye's lens." https://www.epa.gov/ozone-layer-protection/health-and-environmental-effects-ozone-layer-depletion (Accessed 9-18-17)

[21] The human health risks of global warming were well recognized and documented, at least in part, by the agency prior to the arrival of Administrator Pruitt, as outlined in the legacy pages at: https://19january2017snapshot.epa.gov/climate-impacts/climate-impacts-human-health_.html While that page is being updated, "...to reflect EPA's priorities under the leadership of President Trump and Administrator Pruitt," the Agency still notes, "Climate change is having direct and indirect impacts on the health of people. More extreme

The EPA Office of Air and Radiation (OAR) has considerable expertise in both ozone depletion and global warming and has assessed some (but not all) of the 10 chemicals from the perspective of these concerns. OAR can help OCSPP draw on this prior work for its TSCA risk evaluations and perform new assessments for those chemicals whose ozone depletion and global warming impacts have not previously been examined. By addressing these impacts in TSCA risk evaluations, EPA will fulfill the law's goal of providing a comprehensive picture of environmental and health risks across the chemical's life cycle. In particular cases, it may also highlight contributors to ozone depletion and global warming that have been overlooked and may warrant restriction. Whether these impacts can be adequately addressed under the Clean Air Act (CAA) or under TSCA need not be determined in the risk evaluation itself and can be deferred to the later evaluation of risk management options under section 6(a).

VI. EPA RISK EVALUATIONS SHOULD NOT REASSESS USES OF TCE, MC AND NMP THAT WERE FULLY ASSESSED IN ITS PROPOSED SECTION 6(a) RULES

EPA has proposed to ban certain uses of TCE, MC and NMP under section 6(a) of amended TSCA.[22] As the basis for these proposed rules, EPA conducted comprehensive exposure and risk assessments on the targeted uses of the three chemicals. These assessments were subject to public comment and peer review both during their development and again as part of the rulemaking process.

In its scoping documents for the three chemicals, EPA indicates that it intends to rely on the completed assessments and will not "reassess" the targeted uses.[23] We strongly agree with this approach. It would be counterproductive for the Agency reopen these assessments for yet another round of public input and to redo the extensive analysis they contain simply so industry commenters can have another bite at the apple on findings they dislike. Moreover, we believe that the next step in the rulemakings is for EPA to issue final rules as quickly as possible. These rules, once issued, should close the book on the targeted uses and enable EPA to focus its risk evaluations on uses that have not yet been assessed. In its more comprehensive risk evaluations, however, EPA should incorporate its earlier assessments so that the exposures they describe can be accounted for in determining aggregate exposure to the three chemicals.

VII. EPA SHOULD NOT REVISIT DEFINITIVE FINDINGS IN IRIS ASSESSMENTS, WHICH REPRESENT THE AGENCY'S AUTHORITATIVE PEER-REVIEWED DETERMINATIONS OF THE HEALTH EFFECTS OF CHEMICALS

Five of the 10 chemicals – TCE, MC, CTC, PERC and 1,4-dioxane – have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect

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weather events, heat waves, spread of infectious diseases and detrimental impacts on air and water quality are having impacts on our health." https://www.epa.gov/climate-research/human-health-and-climate-change-research (accessed 9-18-17).

[22] Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing under TSCA Section 6(a), 82 Fed. Reg. 7432 (Jan. 19, 2017); Trichloroethylene; Regulation of Certain Uses under TSCA § 6(a), 81 Fed. Reg. 91592 (Dec. 16, 2016) and Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses under TSCA Section 6(a), 82 Fed. Reg. 7464 (Jan. 19, 2017).

[23] See, e.g., EPA. *Scope of the Risk Evaluation for Trichloroethylene,* June 2017, at 33.

years of work by EPA scientists, multiple rounds of public comment, inter and intra-agency consultation, and extensive peer review, often by the Agency's independent Science Advisory Board (SAB) or the National Academy of Sciences (NAS).

Where EPA is conducting a TSCA risk evaluation of a chemical that has already been assessed under IRIS, the conclusions of the IRIS assessment should be presumed to be applicable to the TSCA evaluation as a definitive statement by the Agency of the best available science. To revisit IRIS findings would be inefficient and resource-intensive at a time when the Agency is struggling with workforce and budget reductions. It would also make the three-year statutory deadline for completing risk evaluations even more challenging by greatly expanding the scope of EPA's work effort. Most significantly, reopening IRIS findings would prolong scientific uncertainty on issues that have been addressed and resolved through an authoritative, transparent and inclusive EPA process. Like other Agency actions, IRIS assessments often give rise to differences of opinion and some stakeholders may be disappointed by the outcome. But this does not mean that EPA should reinvent the wheel and provide another bite at the apple on scientific determinations that have been made after thorough deliberation and a robust process.

In sum, the problem formulation documents on the 10 chemicals should make clear that EPA's risk evaluations will rely on previous IRIS assessments in determining health effects that those assessments address.

VIII. IN EVALUATING WORKPLACE RISKS, EPA SHOULD RECOGNIZE THE UNEVEN USE AND EFFECTIVENESS OF ENGINEERING CONTROLS, LABELING AND PERSONAL PROTECTIVE EQUIPMENT IN PREVENTING OCCUPATIONAL EXPOSURE

Several scoping documents indicate that, in its approach to occupational exposure analysis, EPA will "[c]onsider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios."[24] These measures are certainly relevant factors in analyzing occupational exposures. However, it is essential that EPA not presume that they will be effective in preventing exposure in all workplaces and for all employees. In many cases, they may in fact provide limited protection, particularly for short-term poorly trained workers in small shops and workers whose English language skills are challenged.

In its proposed section 6(a) rules for TCE, MC and NMP, EPA explained at some length why label warnings and instructions are not uniformly read, comprehended or followed and thus provide limited protection. This was not a mere opinion on EPA's part but the result of an examination of nearly fifty studies.[25] Based on this review, EPA's conclusions as described in its initial TCE rulemaking were as follows:

> "The Agency determined that warning labels and instructions alone could not mitigate the risks to the extent necessary so that TCE no longer presents the identified unreasonable risks to users. The Agency based this determination on an analysis of 48 relevant studies or meta-analyses, which found that consumers and professionals do not consistently pay attention to

[24] See, for example, US EPA (2017). Scope of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster. Pg. 45

[25] OPPT summarized these studies in a paper entitled *The Effectiveness of Labeling on Hazardous Chemicals and Other Products* (March 2016)(Ref. 33 in rulemaking docket).

labels; consumers and professional users often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies."[26]

In the TCE vapor degreasing proposal, EPA further concluded that comprehension of warnings would be unusually challenging because of the complexity of the information conveyed:

> "EPA found that presenting information about TCE on a label would not adequately address the identified unreasonable risks because the nature of the information the user would need to read, understand, and act upon is extremely complex. It would be challenging to most users to follow or convey the complex product label instructions required to explain how to reduce exposures to the extremely low levels needed to minimize the risk from TCE. Rather than a simple message, the label would need to explain a variety of inter-related factors, including but not limited to the use of local exhaust ventilation, respirators and assigned protection factor for the user and bystanders, and time periods during pregnancy with susceptibility of the developing fetus to acute developmental effects, as well as effects to bystanders. *It is unlikely that label language changes for this use will result in widespread, consistent, and successful adoption of risk reduction measures by users and owners.*[27]

Similarly, EPA cautioned that "there are many documented limitations to successful implementation of respirators", including these well-known problems: [28]

> "Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-face piece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good face piece fit, including those individuals whose beards or sideburns interfere with the face piece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, January 8, 1998). According to OSHA, 'improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health. (63 FR 1189-1190).'"

EPA based these conclusions on expert analyses by OSHA, which has extensive experience with respirators under its workplace standards.

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[26] 81 FR at 91601.
[27] 82 FR 7441 (emphasis added)
[28] 82 FR 7445

The problem formulation documents should explicitly recognize that industrial hygiene controls do not necessarily provide reliable and effective protection from exposure and that the adequacy of these controls needs to be examined on a case-by-case basis in the context of the specific establishments where the chemical is used, the makeup of the worker population in these establishments and the diligence of employers in implementing workplace controls. During problem formulation, EPA should elaborate on how these considerations will be applied for the 10 chemicals.

More generally, when considering occupational exposures, EPA needs to recognize and account for differences in levels of exposure, workplace practices and susceptibility that result in significant gradations in risk, even within a single workplace. In workplaces where chemicals and chemical products are used, exposures typically occur most intensely among a highly exposed subgroup, rather than uniformly across the population of workers. In a vehicle repair shop, for example, chemical-intensive tasks on brakes, engines, and drive-train components are performed by a subset of workers who experience high levels of exposure to aerosolized degreasing solvents, whereas other workers in the same shop who perform diagnostic or electrical work, for example, experience little or no exposure to these solvents. To effectively characterize the "conditions of use" among workers, EPA must account for the levels and duration of exposure—and therefore risk—that occurs within highly exposed subgroups as a consequence of actual workplace conditions, rather than relying on an "average" estimated exposure across a population of workers, based on an assumption of "intended" use.

IX. EPA SHOULD NOT EXCLUDE FROM THE 1,4-DIOXANE EVALUATION ITS PRODUCTION AS A BYPRODUCT OR IMPURITY, WHICH IS A SIGNIFICANT SOURCE OF CONTAMINATION OF WATER SOURCES

The scoping document for 1,4-dioxane takes the unusual approach of precluding any consideration of this substance's manufacture as a byproduct or impurity in EPA's risk evaluation:

> "In the case of 1,4-dioxane, EPA anticipates that production of 1,4-dioxane as a by-product from ethoxylation of other chemicals and presence as a contaminant in industrial, commercial and consumer products will be excluded from the scope of the risk evaluation. These 1,4-dioxane activities will be considered in the scope of the risk evaluation for ethoxylated chemicals. EPA believes its regulatory tools under TSCA section 6(a) are better suited to addressing any unreasonable risks that might arise from these activities through regulation of the activities that generate 1,4-dioxane as an impurity or cause it to be present as a contaminant than they are to addressing them through direct regulation of 1,4-dioxane"[29]

This is a deeply flawed approach that will weaken the 1,4-dioxane risk evaluation and result in inadequate risk reduction during any subsequent rulemaking under section 6(a).

1,4-dioxane is a probable carcinogen that has contaminated drinking water and groundwater in multiple parts of the country, eliciting expressions of concern from many public officials and communities. A recent analysis of data from EPA-mandated monitoring indicates that water supplies for more than 7

[29] Scope of the Risk Evaluation for 1,4-Dioxane, at 8 (June 2017)

million Americans in 27 states contain 1,4-dioxane at levels above those that EPA and other agencies believe present an acceptable cancer risk.[30]

1,4-dioxane's presence in drinking water and groundwater is linked to several pathways of release into the environment. In addition to its manufacture as a chemical product, 1,4-dioxane is a byproduct of plastic production and other chemical manufacturing processes utilizing ethoxylation. Due to its production as a byproduct, it is present as an impurity in several industrial, commercial and consumer products. 1,4-dioxane often is found in the wastewater discharged by industrial facilities and POTWs. Its presence in wastewater is likely attributable not only to intentional production and use activities but to the use and disposal of products in which it is present as an impurity.

If 1,4-dioxane's manufacture as a byproduct and presence in products and waste streams as an impurity are excluded from EPA's risk evaluation, it will have no basis for accounting for these sources of environmental release and will be unable to characterize their contribution to levels of the chemical found in drinking water, surface water and ground water. This will make its assessment of the extent and causes of water contamination incomplete and undermine its ability to conduct an informed evaluation of the options for reducing contamination and risk. Any action it later decides to take under section 6 will thus be based on inadequate information and analysis and, as a result, may be ineffective and under-protective.

Manufacture as a byproduct is plainly within the definition of "conditions of use" in section 3(4) of TSCA. There is no basis in this provision or other parts of the law for differentiating between manufacture as a byproduct and purposeful production and including one in a risk evaluation but excluding the other. And in this instance, there's no evidence (and EPA does not claim) that exposure to and release of 1,4-dioxane as a byproduct and impurity are inconsequential from a risk standpoint.[31]

While EPA suggests that it might be more efficient or effective to address byproduct production of 1,4-dioxane in a separate section 6(a) rulemaking for ethoxylated chemicals, this seems far-fetched. If EPA assesses the contribution of these chemicals to 1,4-dioxane water contamination in the current risk evaluation, it will have a sound basis to regulate their production and use under section 6(a) if they are found to present an unreasonable risk of injury.[32] Otherwise, there is no telling when EPA might mitigate water contamination resulting from byproduct production of 1,4-dioxane production. Thus far, EPA has offered no indication when, if ever, it will make a high-priority designation for ethoxylated chemicals and assess their contribution to the presence of 1,4-dioxane in the environment.

We recommend that during problem formulation, EPA add 1,4-dioxane production as a byproduct and impurity to the scope of its risk evaluation.

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[30] Environmental Working Group, HIDDEN CARCINOGEN TAINTS TAP WATER, CONSUMER PRODUCTS NATIONWIDE (September 2017).

[31] Under our interpretation of section 6(b), EPA could not exclude a condition of use from the risk evaluation scope based on low risk in any event.

[32] Section 6(a) does not limit EPA to regulating purposeful production of a chemical subject to a risk evaluation. It can regulate production by other means so long as it has been assessed in that evaluation and found to present an unreasonable risk.

X. BASED ON THE GENERAL PRINCIPLES OUTLINED ABOVE AND OTHER GAPS IN ITS SCOPING DOCUMENTS, EPA SHOULD AUGMENT THESE DOCUMENTS IN SEVERAL SPECIFIC RESPECTS DURING PROBLEM FORMULATION

Applying the general approaches outlined in these comments and in light of several omissions we identified in individual scoping documents, we recommend that EPA bolster those documents during problem formulation as follows:

1-Bromopropane (nPB)

- In our initial comments to EPA, we specifically identified nPB as being imported by companies whose primary business is supplying the cosmetics industry.[33] While the EPA has noted that authorities such as the State of California have included nPB on lists of chemicals banned in cosmetics, the potential for nPB directly or indirectly (through residues remaining from cleaning manufacturing equipment) to be present in cosmetic products is not addressed as a potential use for further assessment.
- As discussed in detail in Part V of these comments, EPA failed to address the ozone depletion potential of nPB.
- While the scoping document includes references to those exposed to nPB from use of the chemical in consumer products, as well as those co-located with dry cleaning facilities utilizing the chemical, it does not clearly identify people who may be further exposed from chemical residuals, such as those wearing clothing cleaned with nPB or their children. This pathway is not discussed, even though the scoping document for PERC includes it from the similar use of PERC in dry cleaning.

Asbestos

- EPA's scoping document claims that public comments were not received on various imported asbestos containing products available in the United States: "Products available from several online retailers and distributers include brake blocks, aftermarket friction products, roof and non-roof coatings, and gaskets, most of which are imported. No public comments were received regarding these uses." However, we submitted detailed comments highlighting all of these items and more, including other building products. [34]
- EPA's failure to include a lengthy list of legacy uses, as further discussed in Part IV of these comments, is especially problematic for asbestos which was extensively sold and distributed and remains widely present and in use in our buildings and cities.
- The recycling of legacy materials, notably asphalt shingles containing asbestos, is a unique and ongoing use of the substance, and in particular is worthy of additional consideration by the EPA, as discussed in our initial comments.[35]

[33] EPA-HQ-OPPT-2016-0741-0027 at PDF Pages 25, 27, 31.
[34] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 19, 25-27
[35] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 21-22

- There is evidence that asbestos has been present in significant levels in some talc products as the result of colocation of asbestos and talc deposits, as we discussed in our initial comments.[36] This use and ongoing exposure are not addressed in the scoping document.

- The scoping document fails to look at the risks of exposure to those who are upstream to the process of utilizing asbestos in chlor-alkali processing. This would include miners and packaging workers (who, while likely abroad, are still being exposed as a result of the substance's uses in the US considered by the EPA), as well as transportation workers, first responders, and community members who may be exposed in the shipment and transfer of asbestos to the chlor-alkali facilities.

- The absence in the scoping document of total import volumes for asbestos is troubling because it deprives the public of an understanding of the aggregate quantities of asbestos present in the US. In fact, the Asbestos Disease Awareness Organization, along with the Environmental Working Group, released a statement on September 19 that, based on data from the Department of Commerce and US International Trade Commission, 705 metric tons of raw asbestos were imported in 2016, compared to 343 metric tons in 2015. This significant increase in imports is important information that should be given prominence in the problem formulation document for asbestos.

Carbon Tetrachloride (CTC)

- As discussed in detail in Part V of these comments, EPA failed to address the ozone depletion potential and global warming potential of CTC in its scoping document. This is particularly problematic for CTC, as its use as a feedstock or intermediary was exempted from the Montreal Protocol on the false assumption that CTC production would be phased out. In actuality, CTC production is poised for an increase due to its use in HFO manufacture, as we discussed on our initial comments.[37]

- As discussed in detail in Part III of these comments, EPA failed to describe with any specificity how it will look at aggregate and cumulative exposures. In the CTC scoping document, EPA seems to specifically discredit the need for this consideration. The Agency highlights the fact that some individuals may be exposed to CTC through vapor intrusion of ground sources of CTC into their home, but then states that, ". . . this route is not likely to be significant given the agency's identified conditions of use . . ." Clearly, whether the CTC inhaled by a resident is from the vapor intrusion or from an adhesive product, they face potential health risks from it. The Agency must consider all uses and sources of exposure in the risk evaluation in order to accurately assess the human health risk and fulfill its statutory obligations.

Cyclic Aliphatic Bromides Cluster (HBCD)

- As detailed in Part IV of these comments, EPA must not exclude the ongoing use and disposal from past introduction of HBCD in a variety of products. Significant exposures will continue to occur as products incorporating HBCD move through their lifecycle, and these exposures must be considered in the risk evaluation.

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[36] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 18-19

[37] EPA-HQ-OPPT-2016-0733-0023 at PDF pages 4-5, 19

N-Methylpyrrolidone (NMP)

- As we documented in our initial comments to the EPA, NMP has been used in the manufacturing of coating for the insides of aluminum spray cans.[38] Even products not including deliberate addition of NMP may therefore be contaminated with NMP, and this exposure pathway should be considered by the Agency.

- As detailed in Part II of these comments, EPA failed to provide specifics on susceptible subpopulations. While the Agency acknowledges that reproductive effects are to be assessed, considering the well-documented reproductive toxicity of NMP, the Agency needs to better detail how the risks to women of childbearing age will be addressed.

Methylene Chloride (MC)

- While the scoping document includes a use categorization for "other consumer products" including novelty "Drinking Bird" items, we identified an additional item,[39] a "Novelty Christmas Bubbling Night Light" labeled as containing MC but not previously included in EPA's "Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Methylene Chloride." These consumer-oriented uses that are attractive to children illustrate the need to be comprehensive in the determination of "reasonably foreseeable" uses.

XI. EPA MAY NOT PREJUDGE THE ABSENCE OF ADVERSE EFFECTS FOR PARTICULAR END-POINTS AT THE SCOPING STAGE AND SHOULD DEFER SUCH CONCLUSIONS UNTIL THE SYSTEMATIC REVIEW STAGE OF ITS RISK EVALUATION

In some scoping documents, EPA has decided that the subject chemical does not raise concerns for particular endpoints and, therefore, it will not address these end-points in its risk evaluation. Examples are given in the table below where EPA concludes that HBCD, NMP and pigment violet 29 are not genotoxic:

Chemical	Example Text from EPA Scoping Document
HBCD	"Available data suggest that HBCD is not genotoxic. Existing assessments have also concluded, based on genotoxicity information and a limited lifetime study, that HBCD is not carcinogenic (NICNAS, 2012; EINECS, 2008; TemaNord, 2008; OECD, 2007). Unless new information indicates otherwise, EPA does not expect to conduct additional in-depth analysis of genotoxicity or cancer hazards in the risk evaluation of HBCD at this time."[40]
NMP	"NMP is not mutagenic, based on results from bacterial and mammalian *in vitro* tests and *in vivo* systems and is not considered to be carcinogenic (RIVM, 2013; OECD, 2007; WHO, 2001). Unless new information indicates otherwise, EPA does not expect to conduct additional in-depth analysis of genotoxicity and cancer hazards in the NMP risk evaluation."[41]

[38] EPA-HQ-OPPT-2016-0743-0031 at PDF page 18
[39] https://www.amazon.com/Bubble-Nightlight-Novelty-Christmas-Bubbling/dp/B00PV61HXC/
[40] EPA, *Scope of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster, June 2017, at.* 36
[41] EPA, *Scope of the Risk Evaluation for N-Methylpyrrolidone,* June 2017, *at* 36

Pigment violet 29	"Testing for carcinogenicity of Pigment Violet 29 has not been conducted. However, negative genotoxicity results, structure-activity considerations and the expectation of negligible absorption and uptake of Pigment Violet 29 (based on very low solubility), indicate carcinogenicity of Pigment Violet 29 is unlikely. Unless new information indicates otherwise, EPA does not expect to conduct additional, in-depth analyses of genotoxicity and cancer hazards in the risk evaluation of Pigment Violet 29."[42]

EPA cannot reach such definitive conclusions at the scoping stage. The required course under the law is to proceed with a systematic review of the relevant data (a process that EPA strongly endorses) and withhold any conclusions about particular end-points until this review is complete.

In the case of HBCD, for example, a more thorough review would reveal two recent studies indicating carcinogenic potential. One suggests that HBCD could "enhance progression of prostate cancer by modulating growth and migration of LNCaP prostate cells,"[43] and the other concludes the genotoxicity of HBCD is dose-dependent and related to DNA repair.[44] These new studies are examples of the need for EPA to assure that it has fully considered all the available data through the systematic review process in order to avoid premature and possibly incorrect decisions to drop particular end-points at the scoping stage.

XII. PROBLEM FORMULATIONS SHOULD HIGHLIGHT ASPECTS OF USE AND EXPOSURE WHERE AVAILABLE INFORMATION IS INSUFFICIENT AND REQUEST OR REQUIRE SUBMISSION OF THIS INFORMATION BY INDUSTRY

Our own research on the 10 chemicals and the scoping documents themselves confirm that there are significant gaps in the use and exposure information available to EPA and that they will weaken the quality of EPA's risk evaluations unless filled. Although the timeframe for completing risk evaluations is compressed, there is still a window for augmenting the information-base used to conduct them. To take advantage of this opportunity, EPA should include in each problem formulation document a description of information on use and exposure that is lacking and a request that industry and other interested parties submit or obtain that information as expeditiously as possible.

EPA should also signal its readiness to use its mandatory information collection authorities under TSCA to fill data-gaps where voluntary submissions are not timely or adequate. The LCSA expands these authorities and streamlines the process for exercising them, removing the barriers to information development that hamstrung EPA under the old law. For example, section 4 now authorizes EPA to issue orders where necessary to "perform a risk evaluation." Such orders can be used to require industry to develop new information on the frequency, levels and duration of exposure for a chemical's conditions of use. Alternatively, EPA can use its subpoena authority under section 11 to obtain such information that already exists but has not been provided to EPA. EPA should specify in the problem formulation document its roadmap and timetable for filling data gaps using these authorities.

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[42] EPA, *Scope of the Risk Evaluation for Pigment Violet 29*, June 2017, at 29.

[43] Seung-Hee Kim, et al, 2016. Influence of hexabromocyclododecane and 4-nonylphenol on the regulation of cell growth, apoptosis and migration in prostatic cancer cells. Toxicology in Vitro. 32:240-247. April 2016.

[44] Rui Jing Li, et al. Hexabromocyclododecane-induced Genotoxicity in Cultured Human Breast Cells through DNA Damage. Letter to Editor. Biomedical and Environmental Sciences. 30(4): 296-300.

Where the database available for a risk evaluation is incomplete, it is critically important that EPA not equate the absence of data with the absence of risk. For example, if EPA lacks data to assess a chemical's carcinogenicity, its risk evaluation needs to clearly state that cancer risk has not been addressed, that the chemical may or may not present such a risk, and that this end-point is outside the scope of its evaluation because of the absence of data. EPA should make the same disclaimers for conditions of use that cannot be adequately characterized, even by using default assumptions or extrapolation methods, because basic information about the nature of the use and scope and extent of exposure is unavailable.

XIII. EPA NEEDS TO LIMIT REDACTION FROM SCOPING AND PROBLEM FORMULATION DOCUMENTS OF CRITICAL INFORMATION CLAIMED CBI SO THAT TRANSPARENCY AND PUBLIC PARTICIPATION IN THE RISK EVALUATION PROCESS ARE NOT IMPAIRED

The scoping documents omit critical exposure and use information that has been claimed as confidential business information (CBI) that must be withheld from disclosure under TSCA. In some cases, the information is as basic as the total volume of the chemical manufactured and imported in the US. For example, the scoping documents fail to provide total manufacture/import volumes for asbestos, HBCD and pigment violet 29. Not only is this information obtainable in the public domain but it is fundamental to public understanding of the risks posed by these chemicals and, therefore, to informed public participation in the risk evaluation process.[45]

During problem formulation, EPA should make a concerted effort to limit the redaction of CBI-claimed production, use and exposure data that are essential for the transparency of the risk evaluation process. Several tools can be used for this purpose.

First, section 14(b)(3) of TSCA declares that "information not protected from disclosure" includes:

> "any general information describing the manufacturing volumes, expressed as specific aggregated volumes or . . . expressed in ranges."
>
> "a general description of a process used in the manufacture or processing and industrial, commercial or consumer functions and uses of a chemical, substance, mixture or article containing a chemical substance or mixture . . ."

This provision compels the disclosure of much of the information in scoping documents claimed CBI.

Alternatively, section 14(d)(7) provides that the Administrator may disclose information otherwise warranting CBI protection if he or she "determines that disclosure is relevant in a proceeding under this Act." The risk evaluations that EPA is conducting on the 10 chemicals under section 6(b)(2)(A) of TSCA represent a "proceeding" under TSCA. Information submitted by industry on the 10 chemicals is plainly "relevant" to these evaluations because it will inform how EPA assesses exposures and related risks

[45] For asbestos, SCHF and Environmental Health Strategy Center were able to use US government data accessible through the Panjiva database to determine annual asbestos imports over an extended period. As noted above, a more recent analysis of import data by the Asbestos Disease Awareness Organization shows that asbestos imports doubled in 2016, a startling finding that should be central to EPA's risk evaluation because of its implications for exposure to asbestos in the US.

associated with manufacture, processing and downstream commercial and consumer use. Thus, EPA can and should decide to disclose all information on the 10 chemicals notwithstanding any CBI claims.

Finally, to the extent these grounds for disclosure do not apply, EPA should use its authority under section 14(f)(1)(C) to require immediate substantiation of CBI claims for information for which "disclosure would be important to assist the Administrator in conducting risk evaluations . . . under section 6." This provision should be applied broadly to accomplish disclosure of all information that would be of value to the public in commenting on risk evaluations.

CONCLUSION

Our groups appreciate the opportunity to comment on the 10 scoping documents and look forward to continued dialogue with the Agency as it develops problem formulation documents and proceeds with risk evaluations on the 10 chemicals.

If you have any questions, please contact SCHF counsel, Bob Sussman, at bobsussman1@comcast.net or 202-716-0118.

Respectfully submitted,

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September 19, 2017

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families on Risk Evaluation Scoping Documents for Ten Chemical Substances under the Toxic Substances Control Act

Submitted via Regulations.gov (September 19, 2017)

1,4-Dioxane. Docket ID No.: EPA-HQ-OPPT-2016-0723.

1-Bromopropane. Docket ID No.: EPA-HQ-OPPT-2016-0741.

Asbestos. Docket ID No.: EPA-HQ-OPPT-2016-0736.

Carbon Tetrachloride. Docket ID No.: EPA-HQ-OPPT-2016-0733.

Cyclic Aliphatic Bromide Cluster (Hexabromocyclododecane or HBCD). Docket ID No.: EPA-HQ-OPPT-2016-0735.

Methylene Chloride. Docket ID No.: EPA-HQ-OPPT-2016-0742.

N-Methylpyrrolidone (NMP). Docket ID No.: EPA-HQ-OPPT-2016-0743.

Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f]diisoquinoline-1,3,8,10(2H,9H)-tetrone). Docket ID No.: EPA-HQ-OPPT-2016-0725.

Trichloroethylene (TCE). Docket ID No.: EPA-HQ-OPPT-2016-0737.

Tetrachloroethylene (also known as Perchloroethylene). Docket ID No.: EPA-HQ-OPPT-2016-0732.

INTRODUCTION AND SUMMARY

Safer Chemicals, Health Families (SCHF), Earthjustice, Natural Resources Defense Council (NRDC), Environmental Health Strategy Center, Toxic-Free Future and Asbestos Disease Awareness Organization (ADAO) submit these comments on the scoping documents developed by the Environmental Protection Agency (EPA) on the initial 10 chemicals selected for risk evaluations under the newly enacted Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). These organizations are committed to enhancing the safety of chemicals used in homes, workplaces and products and strongly support effective and health-protective implementation of the LCSA.

Through LCSA, Congress amended the Toxic Substances Control Act (TSCA) to establish a new framework for conducting timely, comprehensive and science-based risk evaluations for chemicals of concern. The law provides that EPA's evaluations must be strictly risk-based and must result in a definitive determination of whether the evaluated substance as a whole presents an unreasonable risk of injury to health and the environment across its life cycle, without regard to cost and other non-risk factors.

Congress wanted EPA to launch the risk evaluation process expeditiously. Accordingly, in section 6(b)(2)(A) of TSCA, it directed EPA to assure that evaluations are initiated within six months of the law's enactment on 10 substances drawn from the 2014 TSCA Workplan list. EPA designated these 10 substances on December 19, 2016,[1] and following a public meeting and comment period, released draft scoping documents on June 22. Soon thereafter, EPA announced that it was developing problem formulation documents on the 10 chemicals and would release them for further comment by the end of the year. It also requested comments on the scoping documents in order to inform its approach to problem formulation.[2]

These comments address general issues common to the 10 chemicals as well as several chemical-specific issues. We are submitting our comments to all ten of the EPA dockets. The comments build on earlier submissions by these groups, including our March 15 comments on the scoping process and our July 24 letter to the Agency providing initial reactions to the 10 scoping documents. We have coordinated with a number of other public health and scientific organizations in developing comments on the scoping documents and generally support their recommendations.

The main messages and key recommendations in our comments are as follows:

- Problem formulation can fill gaps in scoping documents and enhance their depth of analysis but cannot be used to remove uses, exposures and hazards from the risk evaluation scope
- EPA should use problem formulation to provide more detail on the potentially exposed and susceptible subpopulations it will consider and how risks to these subpopulations will be determined
- Problem formulations should also describe EPA's strategies for assessing risks from aggregate and cumulative exposures
- Ongoing use and disposal of chemical products that are no longer being manufactured fall within the TSCA definition of "conditions of use" and must be included in problem formulations and assessed in risk evaluations
- Chemicals with ozone depletion and global warming potential pose environmental and health risks that fall within the scope of TSCA risk evaluations
- EPA risk evaluations should not reassess uses of trichloroethylene (TCE), methylene chloride (MC) and N-Methylpyrrolidone (NMP) that were fully assessed in its proposed section 6(a) rules, although these exposure pathways should be included in its determinations of aggregate exposure to these chemicals
- In the course of TSCA risk evaluations, EPA should not revisit definitive findings in IRIS assessments since these assessments represent the Agency's authoritative, peer reviewed determinations on the health effects of the chemicals they address
- In evaluating workplace risks, EPA should recognize and account for the uneven use and effectiveness of engineering controls, labeling and personal protective equipment in preventing occupational exposure and determine risks to workers in situations where these measures are not in place or ineffective
- EPA should not exclude from the 1,4-dioxane evaluation its production as a byproduct or impurity, which is a significant source of contamination of water sources and cancer risk

[1] 81 Federal Register 91927
[2] 82 Fed. Reg. 31,592 (July 7, 2017).

- In order to apply these general principles and fill other gaps in its scoping documents, these documents must be expanded and strengthened in several specific respects during problem formulation
- EPA should not prejudge the absence of adverse effects for particular end-points at the scoping stage but should defer such conclusions until the systematic review phase of its risk evaluation as the law requires
- Problem formulations should highlight aspects of use and exposure where available information is insufficient and request or require submission of this information by industry and other interested parties
- EPA needs to take stronger steps to limit CBI treatment of critical information during the risk evaluation process so that transparency and public participation in that process are not impaired

I. PROBLEM FORMULATION CAN FILL GAPS IN SCOPING DOCUMENTS AND ENHANCE THEIR DEPTH OF ANALYSIS BUT CANNOT BE USED TO REMOVE USES, EXPOSURES AND HAZARDS FROM THE RISK EVALUATION SCOPE

The 10 chemicals undergoing risk evaluations have widespread and substantial exposure and multiple adverse health effects. Comprehensive and health protective assessments of their safety are essential to safeguard communities and vulnerable populations and to set a precedent for strong and effective implementation of the new law. For this reason, our groups made a significant investment in characterizing the use and exposure profiles of several of the 10 chemicals and provided extensive submissions to the Agency to help inform its scoping documents for these chemicals.

The scoping documents represent a considerable amount of work in a short period of time and provide a helpful starting point for the 10 evaluations. However, the July 7 Federal Register notice announcing the availability of the scoping documents acknowledges that the Agency was unable to process all the information gathered during the scoping process and that the scoping documents were not as "refined or specific" as EPA had hoped. We agree with this assessment and believe that the scoping documents contain serious gaps, lack sufficient information on use and exposure, impose questionable limitations on the risk scenarios to be examined and fail to provide a roadmap to key elements of assessment methodology. These shortcomings reduce the utility of the scoping documents in laying the groundwork for well-informed and rigorous risk evaluations.

Given their limitations, we believe that expanding and strengthening the scoping documents through a problem formulation process is appropriate in this instance. However, neither LCSA nor the recently promulgated risk evaluation process rule refers to or authorizes problem formulation. Because it has no basis in the law, we oppose using problem formulation to narrow the scope of risk evaluations by deleting conditions of use, exposure pathways or health or environmental end-points identified in the June scoping documents. Section 6(b)(4)(D) of amended TSCA provides that, "not later than 6 months after the initiation of a risk evaluation," EPA must "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and the potentially exposed or susceptible subpopulations the Administrator expects to consider." EPA met this requirement in its June scoping documents. The law provides no basis for EPA to remove uses, hazards or exposures from a risk

evaluation after its scope has been established in accordance with section 6(b)(4)(D).[3] Since problem formulation is not a recognized step in the risk evaluation process or a substitute for scoping under LCSA, it cannot be used narrow a risk evaluation's scope after-the-fact.

We do support, however, using problem formulation to provide more detail on the conditions of use, potentially exposed and susceptible subpopulations, and exposure pathways that EPA will evaluate as well as further explanation of the methodologies that EPA will use in its analysis of these and other risk assessment elements. This will help better structure the risk evaluations, assure that all relevant information is considered, and characterize more fully the conditions of use to be evaluated – without narrowing the risk evaluation scope.

II. EPA SHOULD USE PROBLEM FORMULATION TO PROVIDE MORE DETAIL ON THE POTENTIALLY EXPOSED AND SUSCEPTIBLE SUBPOPULATIONS IT WILL CONSIDER AND HOW RISKS TO THESE SUBPOPULATIONS WILL BE DETERMINED

One area that would benefit from greater elaboration during problem formulation is the identification of potentially exposed or susceptible subpopulations that require consideration in risk evaluations under TSCA section 6(b)(4)(F). The scoping documents provide nearly identical general "boilerplate" descriptions of such subpopulations. Further particulars on the size, geographic location, demographic characteristics and exposure profile of each subpopulation EPA has identified would provide helpful assurance that the risks to that subpopulation will be characterized with the rigor that TSCA requires.

It is also critical for EPA to spell out the methodology it intends to use to determine the nature and magnitude of the risks that chemicals pose to each subpopulation. Such subpopulations are often comprised of low income and/or people of color and exposed to a disproportionate share of pollution, environmental hazards, and social and economic stressors. Multiple exposures to chemical and non-chemical stressors collectively increase the risk of harm, combined with synergistic effects with other health stressors such as limited access to quality health care.[4,5] EPA's risk evaluations need to fully account for these factors and its problem formulations should explain how it intends to do so.

In regard to greater susceptibility, the following are well-known factors that increase biologic sensitivity or reduce resilience to exposures,[6,7] and should be considered consistently for all 10 chemicals to identify susceptible subpopulations:

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[3] EPA's final risk evaluation rule, in contrast to its proposal, would permit the Agency to select which conditions of use to include in risk evaluation scopes as opposed to including all such uses. 82 Fed. Reg. 33,726 (July 20, 2017). Our groups argued in their comments on the proposal that the law required the Agency to address all conditions of use in its risk evaluations, as was recognized in the Agency's original proposal. Along with several other groups, we are challenging EPA's contrary interpretation in its petition for judicial review of the risk evaluation rule. Regardless of the outcome of this challenge, we believe that EPA has no basis to narrow the risk evaluation to exclude conditions of use once they have been included in its scope.

[4] Morello-Frosch R, Zuk M, Jerrett M, Shamasunder B, Kyle AD. Understanding the cumulative impacts of inequalities in environmental health: Implications for policy. Health Aff. 2011;30(5):879–87.

[5] Vesterinen HM, Morello-Frosch R, Sen S, Zeise L, Woodruff TJ. Cumulative effects of prenatal-exposure to exogenous chemicals and psychosocial stress on fetal growth: Systematic-review of the human and animal evidence. Meliker J, editor. PLoS One. 2017 Jul 12;12(7):e0176331.

[6] Morello-Frosch R, Zuk M, Jerrett M, Shamasunder B, Kyle AD. Understanding the cumulative impacts of inequalities in environmental health: Implications for policy. Health Aff. 2011;30(5):879–87.

Intrinsic/ endogenous factors

- Genetic polymorphisms/ genetics/ genetic makeup
- Health status/ nutritional status/ disease status/ pre-existing conditions
- Prenatal life stage
- Age

Extrinsic factors

- Multiple exposures/ co-exposures
- Race/ ethnicity
- Socioeconomic status (SES)

For example, the prenatal life stage is the most sensitive to developmental and reproductive toxicants, and women of childbearing age should be considered as a susceptible subpopulation for any chemical with such hazards. However, women of reproductive age are not identified as a potential susceptible subpopulation in the scoping documents for pigment violet 29, TCE, NMP, PERC, or HBCD, even though EPA will consider reproductive and developmental toxicity hazards for these chemicals. This omission should be corrected during problem formulation.

III. PROBLEM FORMULATION MUST DESCRIBE EPA'S STRATEGIES FOR ASSESSING RISKS FROM AGGREGATE AND CUMULATIVE EXPOSURES

Problem formulation should also address more fully how EPA intends to address the risks resulting from cumulative and aggregate exposures to each of the 10 chemicals. The scoping documents provide minimal discussion of this essential aspect of risk evaluation design.

Section 6(b)(4)(F)(ii) requires risk evaluations to describe whether aggregate or sentinel exposures to a chemical were considered and the basis for that consideration. To properly apply either or both of these approaches in a risk evaluation, EPA must determine in advance what methodology it will employ and then incorporate it in the risk evaluation design in sufficient detail to describe the key data sources it will use to assess exposure and how they will be used. The scoping documents fail to do this. EPA should remedy this gap in problem formulation.

We believe aggregate exposure assessment will be required for all of the 10 chemicals.[8] The focus of the new law is on determining risk based on all relevant pathways and sources of exposure for the general population and vulnerable subpopulations throughout a chemical's life cycle. Thus, under section 6(b)(4)(F)(i), EPA must "integrate and assess available information on hazards and exposures for *the conditions of use* of the chemical substance" and, under section 6(b)(4)(F)(iv), must "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under *the conditions of use* of the chemical substance." This emphasis on integrating risk and exposure factors across a chemical's conditions of use necessarily requires the Agency to identify all sources of exposure that may affect the general population or specific subpopulations and to determine the overall levels, frequency

[7] National Research Council. Science and Decisions: Advancing Risk Assessment. Washington, D.C.: National Academies Press; 2009.

[8] When analyzing aggregate exposures, "sentinel exposure" may be considered simultaneously, where appropriate. However, these are not mutually exclusive and EPA should not incorporate sentinel to the exclusion of aggregate.

and duration of exposures by each population or subpopulation resulting from this combination of pathways.[9]

EPA has applied the tools of "aggregate exposure assessment" successfully in several programs. For example, the 1996 Food Quality Protection Act (FQPA) directs EPA to examine aggregate exposures when issuing or renewing tolerances for pesticides in food and EPA has longstanding guidance for doing aggregate risk and exposure assessments to meet this requirement.[10]

During problem formulation, EPA should develop a roadmap for each of the 10 chemicals showing what steps it is taking to gather the necessary information for aggregate exposure assessment and how it will calculate or estimate the combined exposures resulting from multiple pathways or uses for the general population and potentially exposed or susceptible subpopulations.

Problem formulations should also address whether and how EPA will use "cumulative risk" methodologies for the first 10 risk evaluations. This, too, is an area that EPA has addressed in several guidance documents.[11] The Agency defines "cumulative risk" as "the combined risks from aggregate exposures (i.e., multiple route exposures) to multiple agents or stressors" and has explained that:

> "In cumulative risk assessments that examine risks posed by multiple chemicals, exposure assessments evaluate a population's chemical exposures through multiple routes of exposure over time. Such assessments may encompass multiple exposure timeframes in which the timing and intensity of exposures to different chemicals are examined relative to each other. It is also important to determine whether the exposures to multiple chemicals can lead to toxicokinetic interactions or toxicodynamic interactions. In addition to providing information about multiple chemical exposures in the general population, these exposure assessments identify potentially susceptible or vulnerable subpopulations in the study area and potentially unique pathways of exposure in those subpopulations."[12]

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[9] Exposures from TSCA-exempt uses such as personal care products or biocides should also be included in scoping documents and risk evaluations because of the need to account for their contribution to aggregate risk, even though regulatory authority over these products is not available under TSCA but derives from other laws administered by EPA or agencies such as FDA. This is now standard practice in implementing the Food Quality Protection Act (FQPA). The scoping documents contain limited and incomplete information on exposures to the listed chemicals from non-TSCA uses.

[10] https://www.epa.gov/sites/production/files/2015-07/documents/aggregate.pdf

[11] E.g., *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity.* U.S. Environmental Protection Agency, Office of Pesticide Programs, Washington, DC. (2002) Available at http://www.epa.gov/oppfead1/trac/science/cumulative_guidance.pdf; *Framework for Cumulative Risk Assessment,* U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Washington, DC. EPA/600/P-02/001F (2004). Available at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=54944.

[12] EPA National Center for Environmental Assessment, *Concepts, Methods and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures and Effects: A Resource Document,* at xxviii (August 2007).

The importance of examining risks posed by multiple chemicals with overlapping pathways of exposure and common adverse health effects was also underscored by the National Academy of Sciences (NAS) in its Phthalates and Cumulative Risk report.[13]

We recommend that, in its problem formulations, EPA should commit to perform cumulative risk assessments whenever a population or subpopulation exposed to the subject chemical is also exposed to other chemicals that have similar health effects. In this situation, total risk to the relevant population or subpopulation will be a function not just of exposure to the subject chemical in isolation but of combined exposure to that chemical and other chemicals which have additive or synergistic health effects.

A compelling case for examining cumulative risks will exist where EPA is in parallel conducting risk evaluations on multiple chemicals within a class that have similar chemical structures, conditions of use and adverse health effects. An example of such a grouping is the four solvents (TCE, PERC, MC and NMP) among the initial 10 chemicals: not only is it likely that workers and consumers are exposed to all or some of these solvents simultaneously but their common hazards (i.e. neurotoxicity, reproductive toxicity) are likely to magnify the risks of such concurrent exposures. The problem formulations for these four chemicals should recognize the need to examine the cumulative risks they present and describe how EPA will evaluate cumulative risk scenarios.

IV. ONGOING USE AND DISPOSAL OF CHEMICAL PRODUCTS THAT ARE NO LONGER BEING MANUFACTURED FALL WITHIN THE TSCA DEFINITION OF "CONDITIONS OF USE" AND MUST BE ASSESSED IN RISK EVALUATIONS

Several of the 10 chemicals – asbestos, perchloroethylene (PERC), TCE, MC, carbon tetrachloride (CTC) and hexabromocyclododecane (HBCD) – contribute to ongoing exposure and risk as a result of historical manufacturing and processing activities that have been discontinued. In many cases, the current and foreseeable risks associated with these activities are significant. Nonetheless, the scoping documents provide limited information about these risk and exposure scenarios and take the position that they are outside the scope of risk evaluations except possibly as a source of information about aggregate exposure. Each scoping document contains this statement:

> "EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. For instance, the conditions of use for purposes of section 6 might reasonably include the use of a chemical substance in insulation where the manufacture, processing or distribution in commerce for that use is prospective or on-going, but would not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical

[13] National Research Council. Committee on the Health Risks of Phthalates, Board on Environmental Studies and Toxicology, Division on Earth and Life Studies. 2008. Phthalates and cumulative risk assessment: the task ahead. Washington, D.C.: National Academies Press.

substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses."[14]

We believe that EPA is incorrectly interpreting the provisions of LCSA. The definition of "conditions of use" in section 3(4) covers the "circumstances . . . under which a chemical substance is . . . known or reasonably foreseen to be . . . used or disposed of." Where a chemical is performing an ongoing *in situ* function as a result of previous manufacturing and processing activity, that function comprises a current "use" of the chemical that is "known" to be occurring.

For example, although asbestos may no longer be sold as insulation, the asbestos insulation installed in millions of US buildings continues to perform insulating functions and thus is a current ongoing "use" of asbestos. Installed asbestos-containing building materials (ACBMs) represent one of the largest sources of asbestos accessible to the general public in the US, and the largest asbestos-exposed population consists of people who occupy buildings and homes with ACBMs. Maintenance and construction activities involving ACBMs are also frequent and widespread and account for the largest present-day increase in mesothelioma illness and death in the US.[15]

Similarly, the Healthy Building Network estimates there are 66-132 million pounds (30,000-60,000 metric tons) of HBCD in insulation in existing buildings.[16] These ongoing insulation uses are and will continue to be critical sources of ongoing exposures. HBCD is also present in cars and furniture as a flame retardant and its use in these long-lived consumer articles will contribute to ongoing exposures for years to come.[17]

Equally important, the disposal of building materials or consumer products containing asbestos or HBCD is an ongoing occurrence as buildings are torn down or remodeled and cars and furniture are replaced. Thus, the resulting releases into the environment and communities comprise a "circumstance . . . under which [these chemicals] are . . . known or reasonably foreseen to be . . . disposed of." As "conditions of use" within the TSCA definition, these activities and the risks they present are likewise required to be addressed in risk evaluations under section 6(b). For both chemicals, the immediate and long-term exposures associated with disposal of *in situ* building materials and products are likely to be widespread and significant well into the future.

To exclude from risk evaluations ongoing and future exposures from *in situ* uses of discontinued products would create a sizable gap in the life-cycle assessments of risk that Congress directed EPA to conduct under the new law. This would deprive the public, scientists and regulators of a comprehensive

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[14] EPA, *Scope of the Risk Evaluation for Asbestos*, June 2017, at 8.

[15] US CDC study, "Malignant Mesothelioma Mortality – United States 1999 to 2005."

[16] Safer Chemicals, Healthy Families et al. Comments to the U.S. Environmental Protection Agency (EPA) on the Scope of its Risk Evaluation for the TSCA Work Plan Chemicals: CYCLIC ALIPHATIC BROMIDE CLUSTER or HEXABROMOCYCLODODECANE (HBCD). March 15, 2017. https://healthybuilding.net/uploads/files/saferchemicals-hbcd.pdf

[17] For chemicals like TCE and PERC, the uses that contributed to widespread contamination of groundwater and drinking water may in fact be uses for which these chemicals are still being sold, requiring EPA to include them in its risk evaluations even under its narrow interpretation of the law.

picture of one of the largest sources of continuing and future risk. One consequence would be that EPA would lack the scientific basis to ban resumption of the sale and distribution of discontinued products containing asbestos, HBCD and similar chemicals despite the unreasonable risks that they present. In addition, decision-makers would be unable to reduce ongoing exposures and impose safeguards against unsafe disposal because they would lack a meaningful risk evaluation to inform these actions. Just as TSCA provides authority to evaluate the risks associated with ongoing exposures from discontinued activities, so it gives EPA the authority under section 6(a) to reduce these risks, yet the Agency would be stymied by the absence of a risk evaluation that provides a basis for such regulation.[18]

In short, EPA must characterize and assess ongoing exposures from the use and disposal of discontinued products and determine the risks they present as part of its risk evaluations on the initial 10 chemicals. The scoping documents provide virtually no discussion of these sources of exposure to the 10 chemicals. Nothing in the law allows EPA to exclude these risks from its evaluations. EPA must correct this omission during problem formulation.

V. OZONE DEPLETION AND GLOBAL WARMING POTENTIAL POSE ENVIRONMENTAL AND HEALTH RISKS THAT FALL WITHIN THE SCOPE OF TSCA RISK EVALUATIONS

In earlier submissions, SCHF and its members highlighted data showing the high ozone depleting potential of MC, CTC and 1-Bromopropane (1-BP).[19] The scoping documents do not address these properties of the three chemicals. Nor do they examine the global warming potential (GWP) of any of the 10 chemicals. These omissions conflict with the express purpose of risk evaluations under section 6(b)(4)(A): to "determine whether a chemical substance presents an unreasonable risk of injury to health *or the environment"* (emphasis added). They also fail to meet the Agency's obligation under section 6(b)(4)(F)(i) to "integrate and assess information . . . that is relevant to specific risks of injury to health *or the environment"* (emphasis added). Ozone depletion and global warming potential clearly pose risks to the environment and they are also recognized risk factors for human health.[20,21] Nothing in the law allows EPA to exclude these risks from its evaluations.

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[18] For some chemicals like lead and asbestos, other laws administered by EPA address handling and disposal of *in situ* materials. The Agency may be able to refer the findings of its risk evaluations to the programs implementing these laws under TSCA section 9(b) in lieu of further regulation under section 6. However, there are no existing laws that address ongoing exposure from use and disposal of discontinued products containing HBCD, perfluorinated chemicals and other substances and therefore the availability of the protections afforded under section 6 of TSCA may be critical to addressing their risks.

[19] See Comments of Safer Chemicals Healthy Families on Risk Evaluation Scoping Documents for Ten Chemical Substances under the Toxic Substances Control Act, March 15, 2017.

[20] The human health risks of ozone depletion are well recognized by the Agency and documented, at least in part, on EPA's webpage, "Health and Environmental Effects of Ozone Layer Depletion:" "Ozone layer depletion increases the amount of UVB that reaches the Earth's surface. Laboratory and epidemiological studies demonstrate that UVB causes non-melanoma skin cancer and plays a major role in malignant melanoma development. In addition, UVB has been linked to the development of cataracts, a clouding of the eye's lens." https://www.epa.gov/ozone-layer-protection/health-and-environmental-effects-ozone-layer-depletion (Accessed 9-18-17)

[21] The human health risks of global warming were well recognized and documented, at least in part, by the agency prior to the arrival of Administrator Pruitt, as outlined in the legacy pages at: https://19january2017snapshot.epa.gov/climate-impacts/climate-impacts-human-health_.html While that page is being updated, "...to reflect EPA's priorities under the leadership of President Trump and Administrator Pruitt," the Agency still notes, "Climate change is having direct and indirect impacts on the health of people. More extreme

The EPA Office of Air and Radiation (OAR) has considerable expertise in both ozone depletion and global warming and has assessed some (but not all) of the 10 chemicals from the perspective of these concerns. OAR can help OCSPP draw on this prior work for its TSCA risk evaluations and perform new assessments for those chemicals whose ozone depletion and global warming impacts have not previously been examined. By addressing these impacts in TSCA risk evaluations, EPA will fulfill the law's goal of providing a comprehensive picture of environmental and health risks across the chemical's life cycle. In particular cases, it may also highlight contributors to ozone depletion and global warming that have been overlooked and may warrant restriction. Whether these impacts can be adequately addressed under the Clean Air Act (CAA) or under TSCA need not be determined in the risk evaluation itself and can be deferred to the later evaluation of risk management options under section 6(a).

VI. EPA RISK EVALUATIONS SHOULD NOT REASSESS USES OF TCE, MC AND NMP THAT WERE FULLY ASSESSED IN ITS PROPOSED SECTION 6(a) RULES

EPA has proposed to ban certain uses of TCE, MC and NMP under section 6(a) of amended TSCA.[22] As the basis for these proposed rules, EPA conducted comprehensive exposure and risk assessments on the targeted uses of the three chemicals. These assessments were subject to public comment and peer review both during their development and again as part of the rulemaking process.

In its scoping documents for the three chemicals, EPA indicates that it intends to rely on the completed assessments and will not "reassess" the targeted uses.[23] We strongly agree with this approach. It would be counterproductive for the Agency reopen these assessments for yet another round of public input and to redo the extensive analysis they contain simply so industry commenters can have another bite at the apple on findings they dislike. Moreover, we believe that the next step in the rulemakings is for EPA to issue final rules as quickly as possible. These rules, once issued, should close the book on the targeted uses and enable EPA to focus its risk evaluations on uses that have not yet been assessed. In its more comprehensive risk evaluations, however, EPA should incorporate its earlier assessments so that the exposures they describe can be accounted for in determining aggregate exposure to the three chemicals.

VII. EPA SHOULD NOT REVISIT DEFINITIVE FINDINGS IN IRIS ASSESSMENTS, WHICH REPRESENT THE AGENCY'S AUTHORITATIVE PEER-REVIEWED DETERMINATIONS OF THE HEALTH EFFECTS OF CHEMICALS

Five of the 10 chemicals – TCE, MC, CTC, PERC and 1,4-dioxane – have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect

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weather events, heat waves, spread of infectious diseases and detrimental impacts on air and water quality are having impacts on our health." https://www.epa.gov/climate-research/human-health-and-climate-change-research (accessed 9-18-17).

[22] Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing under TSCA Section 6(a), 82 Fed. Reg. 7432 (Jan. 19, 2017); Trichloroethylene; Regulation of Certain Uses under TSCA § 6(a), 81 Fed. Reg. 91592 (Dec. 16, 2016) and Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses under TSCA Section 6(a), 82 Fed. Reg. 7464 (Jan. 19, 2017).

[23] See, e.g., EPA. *Scope of the Risk Evaluation for Trichloroethylene,* June 2017, at 33.

years of work by EPA scientists, multiple rounds of public comment, inter and intra-agency consultation, and extensive peer review, often by the Agency's independent Science Advisory Board (SAB) or the National Academy of Sciences (NAS).

Where EPA is conducting a TSCA risk evaluation of a chemical that has already been assessed under IRIS, the conclusions of the IRIS assessment should be presumed to be applicable to the TSCA evaluation as a definitive statement by the Agency of the best available science. To revisit IRIS findings would be inefficient and resource-intensive at a time when the Agency is struggling with workforce and budget reductions. It would also make the three-year statutory deadline for completing risk evaluations even more challenging by greatly expanding the scope of EPA's work effort. Most significantly, reopening IRIS findings would prolong scientific uncertainty on issues that have been addressed and resolved through an authoritative, transparent and inclusive EPA process. Like other Agency actions, IRIS assessments often give rise to differences of opinion and some stakeholders may be disappointed by the outcome. But this does not mean that EPA should reinvent the wheel and provide another bite at the apple on scientific determinations that have been made after thorough deliberation and a robust process.

In sum, the problem formulation documents on the 10 chemicals should make clear that EPA's risk evaluations will rely on previous IRIS assessments in determining health effects that those assessments address.

VIII. IN EVALUATING WORKPLACE RISKS, EPA SHOULD RECOGNIZE THE UNEVEN USE AND EFFECTIVENESS OF ENGINEERING CONTROLS, LABELING AND PERSONAL PROTECTIVE EQUIPMENT IN PREVENTING OCCUPATIONAL EXPOSURE

Several scoping documents indicate that, in its approach to occupational exposure analysis, EPA will "[c]onsider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios."[24] These measures are certainly relevant factors in analyzing occupational exposures. However, it is essential that EPA not presume that they will be effective in preventing exposure in all workplaces and for all employees. In many cases, they may in fact provide limited protection, particularly for short-term poorly trained workers in small shops and workers whose English language skills are challenged.

In its proposed section 6(a) rules for TCE, MC and NMP, EPA explained at some length why label warnings and instructions are not uniformly read, comprehended or followed and thus provide limited protection. This was not a mere opinion on EPA's part but the result of an examination of nearly fifty studies.[25] Based on this review, EPA's conclusions as described in its initial TCE rulemaking were as follows:

> "The Agency determined that warning labels and instructions alone could not mitigate the risks to the extent necessary so that TCE no longer presents the identified unreasonable risks to users. The Agency based this determination on an analysis of 48 relevant studies or meta-analyses, which found that consumers and professionals do not consistently pay attention to

[24] See, for example, US EPA (2017). Scope of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster. Pg. 45

[25] OPPT summarized these studies in a paper entitled *The Effectiveness of Labeling on Hazardous Chemicals and Other Products* (March 2016)(Ref. 33 in rulemaking docket).

labels; consumers and professional users often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies."[26]

In the TCE vapor degreasing proposal, EPA further concluded that comprehension of warnings would be unusually challenging because of the complexity of the information conveyed:

> "EPA found that presenting information about TCE on a label would not adequately address the identified unreasonable risks because the nature of the information the user would need to read, understand, and act upon is extremely complex. It would be challenging to most users to follow or convey the complex product label instructions required to explain how to reduce exposures to the extremely low levels needed to minimize the risk from TCE. Rather than a simple message, the label would need to explain a variety of inter-related factors, including but not limited to the use of local exhaust ventilation, respirators and assigned protection factor for the user and bystanders, and time periods during pregnancy with susceptibility of the developing fetus to acute developmental effects, as well as effects to bystanders. *It is unlikely that label language changes for this use will result in widespread, consistent, and successful adoption of risk reduction measures by users and owners.*[27]

Similarly, EPA cautioned that "there are many documented limitations to successful implementation of respirators", including these well-known problems: [28]

> "Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-face piece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good face piece fit, including those individuals whose beards or sideburns interfere with the face piece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, January 8, 1998). According to OSHA, 'improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health. (63 FR 1189-1190).'"

EPA based these conclusions on expert analyses by OSHA, which has extensive experience with respirators under its workplace standards.

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[26] 81 FR at 91601.
[27] 82 FR 7441 (emphasis added)
[28] 82 FR 7445

The problem formulation documents should explicitly recognize that industrial hygiene controls do not necessarily provide reliable and effective protection from exposure and that the adequacy of these controls needs to be examined on a case-by-case basis in the context of the specific establishments where the chemical is used, the makeup of the worker population in these establishments and the diligence of employers in implementing workplace controls. During problem formulation, EPA should elaborate on how these considerations will be applied for the 10 chemicals.

More generally, when considering occupational exposures, EPA needs to recognize and account for differences in levels of exposure, workplace practices and susceptibility that result in significant gradations in risk, even within a single workplace. In workplaces where chemicals and chemical products are used, exposures typically occur most intensely among a highly exposed subgroup, rather than uniformly across the population of workers. In a vehicle repair shop, for example, chemical-intensive tasks on brakes, engines, and drive-train components are performed by a subset of workers who experience high levels of exposure to aerosolized degreasing solvents, whereas other workers in the same shop who perform diagnostic or electrical work, for example, experience little or no exposure to these solvents. To effectively characterize the "conditions of use" among workers, EPA must account for the levels and duration of exposure—and therefore risk—that occurs within highly exposed subgroups as a consequence of actual workplace conditions, rather than relying on an "average" estimated exposure across a population of workers, based on an assumption of "intended" use.

IX. EPA SHOULD NOT EXCLUDE FROM THE 1,4-DIOXANE EVALUATION ITS PRODUCTION AS A BYPRODUCT OR IMPURITY, WHICH IS A SIGNIFICANT SOURCE OF CONTAMINATION OF WATER SOURCES

The scoping document for 1,4-dioxane takes the unusual approach of precluding any consideration of this substance's manufacture as a byproduct or impurity in EPA's risk evaluation:

> "In the case of 1,4-dioxane, EPA anticipates that production of 1,4-dioxane as a by-product from ethoxylation of other chemicals and presence as a contaminant in industrial, commercial and consumer products will be excluded from the scope of the risk evaluation. These 1,4-dioxane activities will be considered in the scope of the risk evaluation for ethoxylated chemicals. EPA believes its regulatory tools under TSCA section 6(a) are better suited to addressing any unreasonable risks that might arise from these activities through regulation of the activities that generate 1,4-dioxane as an impurity or cause it to be present as a contaminant than they are to addressing them through direct regulation of 1,4-dioxane"[29]

This is a deeply flawed approach that will weaken the 1,4-dioxane risk evaluation and result in inadequate risk reduction during any subsequent rulemaking under section 6(a).

1,4-dioxane is a probable carcinogen that has contaminated drinking water and groundwater in multiple parts of the country, eliciting expressions of concern from many public officials and communities. A recent analysis of data from EPA-mandated monitoring indicates that water supplies for more than 7

[29] Scope of the Risk Evaluation for 1,4-Dioxane, at 8 (June 2017)

million Americans in 27 states contain 1,4-dioxane at levels above those that EPA and other agencies believe present an acceptable cancer risk.[30]

1,4-dioxane's presence in drinking water and groundwater is linked to several pathways of release into the environment. In addition to its manufacture as a chemical product, 1,4-dioxane is a byproduct of plastic production and other chemical manufacturing processes utilizing ethoxylation. Due to its production as a byproduct, it is present as an impurity in several industrial, commercial and consumer products. 1,4-dioxane often is found in the wastewater discharged by industrial facilities and POTWs. Its presence in wastewater is likely attributable not only to intentional production and use activities but to the use and disposal of products in which it is present as an impurity.

If 1,4-dioxane's manufacture as a byproduct and presence in products and waste streams as an impurity are excluded from EPA's risk evaluation, it will have no basis for accounting for these sources of environmental release and will be unable to characterize their contribution to levels of the chemical found in drinking water, surface water and ground water. This will make its assessment of the extent and causes of water contamination incomplete and undermine its ability to conduct an informed evaluation of the options for reducing contamination and risk. Any action it later decides to take under section 6 will thus be based on inadequate information and analysis and, as a result, may be ineffective and under-protective.

Manufacture as a byproduct is plainly within the definition of "conditions of use" in section 3(4) of TSCA. There is no basis in this provision or other parts of the law for differentiating between manufacture as a byproduct and purposeful production and including one in a risk evaluation but excluding the other. And in this instance, there's no evidence (and EPA does not claim) that exposure to and release of 1,4-dioxane as a byproduct and impurity are inconsequential from a risk standpoint.[31]

While EPA suggests that it might be more efficient or effective to address byproduct production of 1,4-dioxane in a separate section 6(a) rulemaking for ethoxylated chemicals, this seems far-fetched. If EPA assesses the contribution of these chemicals to 1,4-dioxane water contamination in the current risk evaluation, it will have a sound basis to regulate their production and use under section 6(a) if they are found to present an unreasonable risk of injury.[32] Otherwise, there is no telling when EPA might mitigate water contamination resulting from byproduct production of 1,4-dioxane production. Thus far, EPA has offered no indication when, if ever, it will make a high-priority designation for ethoxylated chemicals and assess their contribution to the presence of 1,4-dioxane in the environment.

We recommend that during problem formulation, EPA add 1,4-dioxane production as a byproduct and impurity to the scope of its risk evaluation.

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[30] Environmental Working Group, HIDDEN CARCINOGEN TAINTS TAP WATER, CONSUMER PRODUCTS NATIONWIDE (September 2017).

[31] Under our interpretation of section 6(b), EPA could not exclude a condition of use from the risk evaluation scope based on low risk in any event.

[32] Section 6(a) does not limit EPA to regulating purposeful production of a chemical subject to a risk evaluation. It can regulate production by other means so long as it has been assessed in that evaluation and found to present an unreasonable risk.

X. BASED ON THE GENERAL PRINCIPLES OUTLINED ABOVE AND OTHER GAPS IN ITS SCOPING DOCUMENTS, EPA SHOULD AUGMENT THESE DOCUMENTS IN SEVERAL SPECIFIC RESPECTS DURING PROBLEM FORMULATION

Applying the general approaches outlined in these comments and in light of several omissions we identified in individual scoping documents, we recommend that EPA bolster those documents during problem formulation as follows:

1-Bromopropane (nPB)

- In our initial comments to EPA, we specifically identified nPB as being imported by companies whose primary business is supplying the cosmetics industry.[33] While the EPA has noted that authorities such as the State of California have included nPB on lists of chemicals banned in cosmetics, the potential for nPB directly or indirectly (through residues remaining from cleaning manufacturing equipment) to be present in cosmetic products is not addressed as a potential use for further assessment.
- As discussed in detail in Part V of these comments, EPA failed to address the ozone depletion potential of nPB.
- While the scoping document includes references to those exposed to nPB from use of the chemical in consumer products, as well as those co-located with dry cleaning facilities utilizing the chemical, it does not clearly identify people who may be further exposed from chemical residuals, such as those wearing clothing cleaned with nPB or their children. This pathway is not discussed, even though the scoping document for PERC includes it from the similar use of PERC in dry cleaning.

Asbestos

- EPA's scoping document claims that public comments were not received on various imported asbestos containing products available in the United States: "Products available from several online retailers and distributers include brake blocks, aftermarket friction products, roof and non-roof coatings, and gaskets, most of which are imported. No public comments were received regarding these uses." However, we submitted detailed comments highlighting all of these items and more, including other building products. [34]
- EPA's failure to include a lengthy list of legacy uses, as further discussed in Part IV of these comments, is especially problematic for asbestos which was extensively sold and distributed and remains widely present and in use in our buildings and cities.
- The recycling of legacy materials, notably asphalt shingles containing asbestos, is a unique and ongoing use of the substance, and in particular is worthy of additional consideration by the EPA, as discussed in our initial comments.[35]

[33] EPA-HQ-OPPT-2016-0741-0027 at PDF Pages 25, 27, 31.
[34] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 19, 25-27
[35] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 21-22

- There is evidence that asbestos has been present in significant levels in some talc products as the result of colocation of asbestos and talc deposits, as we discussed in our initial comments.[36] This use and ongoing exposure are not addressed in the scoping document.

- The scoping document fails to look at the risks of exposure to those who are upstream to the process of utilizing asbestos in chlor-alkali processing. This would include miners and packaging workers (who, while likely abroad, are still being exposed as a result of the substance's uses in the US considered by the EPA), as well as transportation workers, first responders, and community members who may be exposed in the shipment and transfer of asbestos to the chlor-alkali facilities.

- The absence in the scoping document of total import volumes for asbestos is troubling because it deprives the public of an understanding of the aggregate quantities of asbestos present in the US. In fact, the Asbestos Disease Awareness Organization, along with the Environmental Working Group, released a statement on September 19 that, based on data from the Department of Commerce and US International Trade Commission, 705 metric tons of raw asbestos were imported in 2016, compared to 343 metric tons in 2015. This significant increase in imports is important information that should be given prominence in the problem formulation document for asbestos.

Carbon Tetrachloride (CTC)

- As discussed in detail in Part V of these comments, EPA failed to address the ozone depletion potential and global warming potential of CTC in its scoping document. This is particularly problematic for CTC, as its use as a feedstock or intermediary was exempted from the Montreal Protocol on the false assumption that CTC production would be phased out. In actuality, CTC production is poised for an increase due to its use in HFO manufacture, as we discussed on our initial comments.[37]

- As discussed in detail in Part III of these comments, EPA failed to describe with any specificity how it will look at aggregate and cumulative exposures. In the CTC scoping document, EPA seems to specifically discredit the need for this consideration. The Agency highlights the fact that some individuals may be exposed to CTC through vapor intrusion of ground sources of CTC into their home, but then states that, ". . . this route is not likely to be significant given the agency's identified conditions of use . . ." Clearly, whether the CTC inhaled by a resident is from the vapor intrusion or from an adhesive product, they face potential health risks from it. The Agency must consider all uses and sources of exposure in the risk evaluation in order to accurately assess the human health risk and fulfill its statutory obligations.

Cyclic Aliphatic Bromides Cluster (HBCD)

- As detailed in Part IV of these comments, EPA must not exclude the ongoing use and disposal from past introduction of HBCD in a variety of products. Significant exposures will continue to occur as products incorporating HBCD move through their lifecycle, and these exposures must be considered in the risk evaluation.

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[36] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 18-19

[37] EPA-HQ-OPPT-2016-0733-0023 at PDF pages 4-5, 19

N-Methylpyrrolidone (NMP)

- As we documented in our initial comments to the EPA, NMP has been used in the manufacturing of coating for the insides of aluminum spray cans.[38] Even products not including deliberate addition of NMP may therefore be contaminated with NMP, and this exposure pathway should be considered by the Agency.

- As detailed in Part II of these comments, EPA failed to provide specifics on susceptible subpopulations. While the Agency acknowledges that reproductive effects are to be assessed, considering the well-documented reproductive toxicity of NMP, the Agency needs to better detail how the risks to women of childbearing age will be addressed.

Methylene Chloride (MC)

- While the scoping document includes a use categorization for "other consumer products" including novelty "Drinking Bird" items, we identified an additional item,[39] a "Novelty Christmas Bubbling Night Light" labeled as containing MC but not previously included in EPA's "Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Methylene Chloride." These consumer-oriented uses that are attractive to children illustrate the need to be comprehensive in the determination of "reasonably foreseeable" uses.

XI. EPA MAY NOT PREJUDGE THE ABSENCE OF ADVERSE EFFECTS FOR PARTICULAR END-POINTS AT THE SCOPING STAGE AND SHOULD DEFER SUCH CONCLUSIONS UNTIL THE SYSTEMATIC REVIEW STAGE OF ITS RISK EVALUATION

In some scoping documents, EPA has decided that the subject chemical does not raise concerns for particular endpoints and, therefore, it will not address these end-points in its risk evaluation. Examples are given in the table below where EPA concludes that HBCD, NMP and pigment violet 29 are not genotoxic:

Chemical	Example Text from EPA Scoping Document
HBCD	"Available data suggest that HBCD is not genotoxic. Existing assessments have also concluded, based on genotoxicity information and a limited lifetime study, that HBCD is not carcinogenic (NICNAS, 2012; EINECS, 2008; TemaNord, 2008; OECD, 2007). Unless new information indicates otherwise, EPA does not expect to conduct additional in-depth analysis of genotoxicity or cancer hazards in the risk evaluation of HBCD at this time."[40]
NMP	"NMP is not mutagenic, based on results from bacterial and mammalian *in vitro* tests and *in vivo* systems and is not considered to be carcinogenic (RIVM, 2013; OECD, 2007; WHO, 2001). Unless new information indicates otherwise, EPA does not expect to conduct additional in-depth analysis of genotoxicity and cancer hazards in the NMP risk evaluation."[41]

[38] EPA-HQ-OPPT-2016-0743-0031 at PDF page 18
[39] https://www.amazon.com/Bubble-Nightlight-Novelty-Christmas-Bubbling/dp/B00PV61HXC/
[40] EPA, *Scope of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster, June 2017, at.* 36
[41] EPA, *Scope of the Risk Evaluation for N-Methylpyrrolidone,* June 2017, *at* 36

Pigment violet 29	"Testing for carcinogenicity of Pigment Violet 29 has not been conducted. However, negative genotoxicity results, structure-activity considerations and the expectation of negligible absorption and uptake of Pigment Violet 29 (based on very low solubility), indicate carcinogenicity of Pigment Violet 29 is unlikely. Unless new information indicates otherwise, EPA does not expect to conduct additional, in-depth analyses of genotoxicity and cancer hazards in the risk evaluation of Pigment Violet 29."[42]

EPA cannot reach such definitive conclusions at the scoping stage. The required course under the law is to proceed with a systematic review of the relevant data (a process that EPA strongly endorses) and withhold any conclusions about particular end-points until this review is complete.

In the case of HBCD, for example, a more thorough review would reveal two recent studies indicating carcinogenic potential. One suggests that HBCD could "enhance progression of prostate cancer by modulating growth and migration of LNCaP prostate cells,"[43] and the other concludes the genotoxicity of HBCD is dose-dependent and related to DNA repair.[44] These new studies are examples of the need for EPA to assure that it has fully considered all the available data through the systematic review process in order to avoid premature and possibly incorrect decisions to drop particular end-points at the scoping stage.

XII. PROBLEM FORMULATIONS SHOULD HIGHLIGHT ASPECTS OF USE AND EXPOSURE WHERE AVAILABLE INFORMATION IS INSUFFICIENT AND REQUEST OR REQUIRE SUBMISSION OF THIS INFORMATION BY INDUSTRY

Our own research on the 10 chemicals and the scoping documents themselves confirm that there are significant gaps in the use and exposure information available to EPA and that they will weaken the quality of EPA's risk evaluations unless filled. Although the timeframe for completing risk evaluations is compressed, there is still a window for augmenting the information-base used to conduct them. To take advantage of this opportunity, EPA should include in each problem formulation document a description of information on use and exposure that is lacking and a request that industry and other interested parties submit or obtain that information as expeditiously as possible.

EPA should also signal its readiness to use its mandatory information collection authorities under TSCA to fill data-gaps where voluntary submissions are not timely or adequate. The LCSA expands these authorities and streamlines the process for exercising them, removing the barriers to information development that hamstrung EPA under the old law. For example, section 4 now authorizes EPA to issue orders where necessary to "perform a risk evaluation." Such orders can be used to require industry to develop new information on the frequency, levels and duration of exposure for a chemical's conditions of use. Alternatively, EPA can use its subpoena authority under section 11 to obtain such information that already exists but has not been provided to EPA. EPA should specify in the problem formulation document its roadmap and timetable for filling data gaps using these authorities.

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[42] EPA, *Scope of the Risk Evaluation for Pigment Violet 29*, June 2017, at 29.

[43] Seung-Hee Kim, et al, 2016. Influence of hexabromocyclododecane and 4-nonylphenol on the regulation of cell growth, apoptosis and migration in prostatic cancer cells. Toxicology in Vitro. 32:240-247. April 2016.

[44] Rui Jing Li, et al. Hexabromocyclododecane-induced Genotoxicity in Cultured Human Breast Cells through DNA Damage. Letter to Editor. Biomedical and Environmental Sciences. 30(4): 296-300.

Where the database available for a risk evaluation is incomplete, it is critically important that EPA not equate the absence of data with the absence of risk. For example, if EPA lacks data to assess a chemical's carcinogenicity, its risk evaluation needs to clearly state that cancer risk has not been addressed, that the chemical may or may not present such a risk, and that this end-point is outside the scope of its evaluation because of the absence of data. EPA should make the same disclaimers for conditions of use that cannot be adequately characterized, even by using default assumptions or extrapolation methods, because basic information about the nature of the use and scope and extent of exposure is unavailable.

XIII. EPA NEEDS TO LIMIT REDACTION FROM SCOPING AND PROBLEM FORMULATION DOCUMENTS OF CRITICAL INFORMATION CLAIMED CBI SO THAT TRANSPARENCY AND PUBLIC PARTICIPATION IN THE RISK EVALUATION PROCESS ARE NOT IMPAIRED

The scoping documents omit critical exposure and use information that has been claimed as confidential business information (CBI) that must be withheld from disclosure under TSCA. In some cases, the information is as basic as the total volume of the chemical manufactured and imported in the US. For example, the scoping documents fail to provide total manufacture/import volumes for asbestos, HBCD and pigment violet 29. Not only is this information obtainable in the public domain but it is fundamental to public understanding of the risks posed by these chemicals and, therefore, to informed public participation in the risk evaluation process.[45]

During problem formulation, EPA should make a concerted effort to limit the redaction of CBI-claimed production, use and exposure data that are essential for the transparency of the risk evaluation process. Several tools can be used for this purpose.

First, section 14(b)(3) of TSCA declares that "information not protected from disclosure" includes:

> "any general information describing the manufacturing volumes, expressed as specific aggregated volumes or . . . expressed in ranges."
>
> "a general description of a process used in the manufacture or processing and industrial, commercial or consumer functions and uses of a chemical, substance, mixture or article containing a chemical substance or mixture . . ."

This provision compels the disclosure of much of the information in scoping documents claimed CBI.

Alternatively, section 14(d)(7) provides that the Administrator may disclose information otherwise warranting CBI protection if he or she "determines that disclosure is relevant in a proceeding under this Act." The risk evaluations that EPA is conducting on the 10 chemicals under section 6(b)(2)(A) of TSCA represent a "proceeding" under TSCA. Information submitted by industry on the 10 chemicals is plainly "relevant" to these evaluations because it will inform how EPA assesses exposures and related risks

[45] For asbestos, SCHF and Environmental Health Strategy Center were able to use US government data accessible through the Panjiva database to determine annual asbestos imports over an extended period. As noted above, a more recent analysis of import data by the Asbestos Disease Awareness Organization shows that asbestos imports doubled in 2016, a startling finding that should be central to EPA's risk evaluation because of its implications for exposure to asbestos in the US.

associated with manufacture, processing and downstream commercial and consumer use. Thus, EPA can and should decide to disclose all information on the 10 chemicals notwithstanding any CBI claims.

Finally, to the extent these grounds for disclosure do not apply, EPA should use its authority under section 14(f)(1)(C) to require immediate substantiation of CBI claims for information for which "disclosure would be important to assist the Administrator in conducting risk evaluations . . . under section 6." This provision should be applied broadly to accomplish disclosure of all information that would be of value to the public in commenting on risk evaluations.

CONCLUSION

Our groups appreciate the opportunity to comment on the 10 scoping documents and look forward to continued dialogue with the Agency as it develops problem formulation documents and proceeds with risk evaluations on the 10 chemicals.

If you have any questions, please contact SCHF counsel, Bob Sussman, at bobsussman1@comcast.net or 202-716-0118.

Respectfully submitted,

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September 19, 2017

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families on Risk Evaluation Scoping Documents for Ten Chemical Substances under the Toxic Substances Control Act

Submitted via Regulations.gov (September 19, 2017)

1,4-Dioxane. Docket ID No.: EPA-HQ-OPPT-2016-0723.

1-Bromopropane. Docket ID No.: EPA-HQ-OPPT-2016-0741.

Asbestos. Docket ID No.: EPA-HQ-OPPT-2016-0736.

Carbon Tetrachloride. Docket ID No.: EPA-HQ-OPPT-2016-0733.

Cyclic Aliphatic Bromide Cluster (Hexabromocyclododecane or HBCD). Docket ID No.: EPA-HQ-OPPT-2016-0735.

Methylene Chloride. Docket ID No.: EPA-HQ-OPPT-2016-0742.

N-Methylpyrrolidone (NMP). Docket ID No.: EPA-HQ-OPPT-2016-0743.

Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f]diisoquinoline-1,3,8,10(2H,9H)-tetrone). Docket ID No.: EPA-HQ-OPPT-2016-0725.

Trichloroethylene (TCE). Docket ID No.: EPA-HQ-OPPT-2016-0737.

Tetrachloroethylene (also known as Perchloroethylene). Docket ID No.: EPA-HQ-OPPT-2016-0732.

INTRODUCTION AND SUMMARY

Safer Chemicals, Health Families (SCHF), Earthjustice, Natural Resources Defense Council (NRDC), Environmental Health Strategy Center, Toxic-Free Future and Asbestos Disease Awareness Organization (ADAO) submit these comments on the scoping documents developed by the Environmental Protection Agency (EPA) on the initial 10 chemicals selected for risk evaluations under the newly enacted Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). These organizations are committed to enhancing the safety of chemicals used in homes, workplaces and products and strongly support effective and health-protective implementation of the LCSA.

Through LCSA, Congress amended the Toxic Substances Control Act (TSCA) to establish a new framework for conducting timely, comprehensive and science-based risk evaluations for chemicals of concern. The law provides that EPA's evaluations must be strictly risk-based and must result in a definitive determination of whether the evaluated substance as a whole presents an unreasonable risk of injury to health and the environment across its life cycle, without regard to cost and other non-risk factors.

Congress wanted EPA to launch the risk evaluation process expeditiously. Accordingly, in section 6(b)(2)(A) of TSCA, it directed EPA to assure that evaluations are initiated within six months of the law's enactment on 10 substances drawn from the 2014 TSCA Workplan list. EPA designated these 10 substances on December 19, 2016,[1] and following a public meeting and comment period, released draft scoping documents on June 22. Soon thereafter, EPA announced that it was developing problem formulation documents on the 10 chemicals and would release them for further comment by the end of the year. It also requested comments on the scoping documents in order to inform its approach to problem formulation.[2]

These comments address general issues common to the 10 chemicals as well as several chemical-specific issues. We are submitting our comments to all ten of the EPA dockets. The comments build on earlier submissions by these groups, including our March 15 comments on the scoping process and our July 24 letter to the Agency providing initial reactions to the 10 scoping documents. We have coordinated with a number of other public health and scientific organizations in developing comments on the scoping documents and generally support their recommendations.

The main messages and key recommendations in our comments are as follows:

- Problem formulation can fill gaps in scoping documents and enhance their depth of analysis but cannot be used to remove uses, exposures and hazards from the risk evaluation scope
- EPA should use problem formulation to provide more detail on the potentially exposed and susceptible subpopulations it will consider and how risks to these subpopulations will be determined
- Problem formulations should also describe EPA's strategies for assessing risks from aggregate and cumulative exposures
- Ongoing use and disposal of chemical products that are no longer being manufactured fall within the TSCA definition of "conditions of use" and must be included in problem formulations and assessed in risk evaluations
- Chemicals with ozone depletion and global warming potential pose environmental and health risks that fall within the scope of TSCA risk evaluations
- EPA risk evaluations should not reassess uses of trichloroethylene (TCE), methylene chloride (MC) and N-Methylpyrrolidone (NMP) that were fully assessed in its proposed section 6(a) rules, although these exposure pathways should be included in its determinations of aggregate exposure to these chemicals
- In the course of TSCA risk evaluations, EPA should not revisit definitive findings in IRIS assessments since these assessments represent the Agency's authoritative, peer reviewed determinations on the health effects of the chemicals they address
- In evaluating workplace risks, EPA should recognize and account for the uneven use and effectiveness of engineering controls, labeling and personal protective equipment in preventing occupational exposure and determine risks to workers in situations where these measures are not in place or ineffective
- EPA should not exclude from the 1,4-dioxane evaluation its production as a byproduct or impurity, which is a significant source of contamination of water sources and cancer risk

[1] 81 Federal Register 91927
[2] 82 Fed. Reg. 31,592 (July 7, 2017).

- In order to apply these general principles and fill other gaps in its scoping documents, these documents must be expanded and strengthened in several specific respects during problem formulation
- EPA should not prejudge the absence of adverse effects for particular end-points at the scoping stage but should defer such conclusions until the systematic review phase of its risk evaluation as the law requires
- Problem formulations should highlight aspects of use and exposure where available information is insufficient and request or require submission of this information by industry and other interested parties
- EPA needs to take stronger steps to limit CBI treatment of critical information during the risk evaluation process so that transparency and public participation in that process are not impaired

I. PROBLEM FORMULATION CAN FILL GAPS IN SCOPING DOCUMENTS AND ENHANCE THEIR DEPTH OF ANALYSIS BUT CANNOT BE USED TO REMOVE USES, EXPOSURES AND HAZARDS FROM THE RISK EVALUATION SCOPE

The 10 chemicals undergoing risk evaluations have widespread and substantial exposure and multiple adverse health effects. Comprehensive and health protective assessments of their safety are essential to safeguard communities and vulnerable populations and to set a precedent for strong and effective implementation of the new law. For this reason, our groups made a significant investment in characterizing the use and exposure profiles of several of the 10 chemicals and provided extensive submissions to the Agency to help inform its scoping documents for these chemicals.

The scoping documents represent a considerable amount of work in a short period of time and provide a helpful starting point for the 10 evaluations. However, the July 7 Federal Register notice announcing the availability of the scoping documents acknowledges that the Agency was unable to process all the information gathered during the scoping process and that the scoping documents were not as "refined or specific" as EPA had hoped. We agree with this assessment and believe that the scoping documents contain serious gaps, lack sufficient information on use and exposure, impose questionable limitations on the risk scenarios to be examined and fail to provide a roadmap to key elements of assessment methodology. These shortcomings reduce the utility of the scoping documents in laying the groundwork for well-informed and rigorous risk evaluations.

Given their limitations, we believe that expanding and strengthening the scoping documents through a problem formulation process is appropriate in this instance. However, neither LCSA nor the recently promulgated risk evaluation process rule refers to or authorizes problem formulation. Because it has no basis in the law, we oppose using problem formulation to narrow the scope of risk evaluations by deleting conditions of use, exposure pathways or health or environmental end-points identified in the June scoping documents. Section 6(b)(4)(D) of amended TSCA provides that, "not later than 6 months after the initiation of a risk evaluation," EPA must "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and the potentially exposed or susceptible subpopulations the Administrator expects to consider." EPA met this requirement in its June scoping documents. The law provides no basis for EPA to remove uses, hazards or exposures from a risk

evaluation after its scope has been established in accordance with section 6(b)(4)(D).[3] Since problem formulation is not a recognized step in the risk evaluation process or a substitute for scoping under LCSA, it cannot be used narrow a risk evaluation's scope after-the-fact.

We do support, however, using problem formulation to provide more detail on the conditions of use, potentially exposed and susceptible subpopulations, and exposure pathways that EPA will evaluate as well as further explanation of the methodologies that EPA will use in its analysis of these and other risk assessment elements. This will help better structure the risk evaluations, assure that all relevant information is considered, and characterize more fully the conditions of use to be evaluated – without narrowing the risk evaluation scope.

II. EPA SHOULD USE PROBLEM FORMULATION TO PROVIDE MORE DETAIL ON THE POTENTIALLY EXPOSED AND SUSCEPTIBLE SUBPOPULATIONS IT WILL CONSIDER AND HOW RISKS TO THESE SUBPOPULATIONS WILL BE DETERMINED

One area that would benefit from greater elaboration during problem formulation is the identification of potentially exposed or susceptible subpopulations that require consideration in risk evaluations under TSCA section 6(b)(4)(F). The scoping documents provide nearly identical general "boilerplate" descriptions of such subpopulations. Further particulars on the size, geographic location, demographic characteristics and exposure profile of each subpopulation EPA has identified would provide helpful assurance that the risks to that subpopulation will be characterized with the rigor that TSCA requires.

It is also critical for EPA to spell out the methodology it intends to use to determine the nature and magnitude of the risks that chemicals pose to each subpopulation. Such subpopulations are often comprised of low income and/or people of color and exposed to a disproportionate share of pollution, environmental hazards, and social and economic stressors. Multiple exposures to chemical and non-chemical stressors collectively increase the risk of harm, combined with synergistic effects with other health stressors such as limited access to quality health care.[4,5] EPA's risk evaluations need to fully account for these factors and its problem formulations should explain how it intends to do so.

In regard to greater susceptibility, the following are well-known factors that increase biologic sensitivity or reduce resilience to exposures,[6,7] and should be considered consistently for all 10 chemicals to identify susceptible subpopulations:

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[3] EPA's final risk evaluation rule, in contrast to its proposal, would permit the Agency to select which conditions of use to include in risk evaluation scopes as opposed to including all such uses. 82 Fed. Reg. 33,726 (July 20, 2017). Our groups argued in their comments on the proposal that the law required the Agency to address all conditions of use in its risk evaluations, as was recognized in the Agency's original proposal. Along with several other groups, we are challenging EPA's contrary interpretation in its petition for judicial review of the risk evaluation rule. Regardless of the outcome of this challenge, we believe that EPA has no basis to narrow the risk evaluation to exclude conditions of use once they have been included in its scope.

[4] Morello-Frosch R, Zuk M, Jerrett M, Shamasunder B, Kyle AD. Understanding the cumulative impacts of inequalities in environmental health: Implications for policy. Health Aff. 2011;30(5):879–87.

[5] Vesterinen HM, Morello-Frosch R, Sen S, Zeise L, Woodruff TJ. Cumulative effects of prenatal-exposure to exogenous chemicals and psychosocial stress on fetal growth: Systematic-review of the human and animal evidence. Meliker J, editor. PLoS One. 2017 Jul 12;12(7):e0176331.

[6] Morello-Frosch R, Zuk M, Jerrett M, Shamasunder B, Kyle AD. Understanding the cumulative impacts of inequalities in environmental health: Implications for policy. Health Aff. 2011;30(5):879–87.

Intrinsic/ endogenous factors

- Genetic polymorphisms/ genetics/ genetic makeup
- Health status/ nutritional status/ disease status/ pre-existing conditions
- Prenatal life stage
- Age

Extrinsic factors

- Multiple exposures/ co-exposures
- Race/ ethnicity
- Socioeconomic status (SES)

For example, the prenatal life stage is the most sensitive to developmental and reproductive toxicants, and women of childbearing age should be considered as a susceptible subpopulation for any chemical with such hazards. However, women of reproductive age are not identified as a potential susceptible subpopulation in the scoping documents for pigment violet 29, TCE, NMP, PERC, or HBCD, even though EPA will consider reproductive and developmental toxicity hazards for these chemicals. This omission should be corrected during problem formulation.

III. PROBLEM FORMULATION MUST DESCRIBE EPA'S STRATEGIES FOR ASSESSING RISKS FROM AGGREGATE AND CUMULATIVE EXPOSURES

Problem formulation should also address more fully how EPA intends to address the risks resulting from cumulative and aggregate exposures to each of the 10 chemicals. The scoping documents provide minimal discussion of this essential aspect of risk evaluation design.

Section 6(b)(4)(F)(ii) requires risk evaluations to describe whether aggregate or sentinel exposures to a chemical were considered and the basis for that consideration. To properly apply either or both of these approaches in a risk evaluation, EPA must determine in advance what methodology it will employ and then incorporate it in the risk evaluation design in sufficient detail to describe the key data sources it will use to assess exposure and how they will be used. The scoping documents fail to do this. EPA should remedy this gap in problem formulation.

We believe aggregate exposure assessment will be required for all of the 10 chemicals.[8] The focus of the new law is on determining risk based on all relevant pathways and sources of exposure for the general population and vulnerable subpopulations throughout a chemical's life cycle. Thus, under section 6(b)(4)(F)(i), EPA must "integrate and assess available information on hazards and exposures for *the conditions of use* of the chemical substance" and, under section 6(b)(4)(F)(iv), must "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under *the conditions of use* of the chemical substance." This emphasis on integrating risk and exposure factors across a chemical's conditions of use necessarily requires the Agency to identify all sources of exposure that may affect the general population or specific subpopulations and to determine the overall levels, frequency

[7] National Research Council. Science and Decisions: Advancing Risk Assessment. Washington, D.C.: National Academies Press; 2009.

[8] When analyzing aggregate exposures, "sentinel exposure" may be considered simultaneously, where appropriate. However, these are not mutually exclusive and EPA should not incorporate sentinel to the exclusion of aggregate.

and duration of exposures by each population or subpopulation resulting from this combination of pathways.[9]

EPA has applied the tools of "aggregate exposure assessment" successfully in several programs. For example, the 1996 Food Quality Protection Act (FQPA) directs EPA to examine aggregate exposures when issuing or renewing tolerances for pesticides in food and EPA has longstanding guidance for doing aggregate risk and exposure assessments to meet this requirement.[10]

During problem formulation, EPA should develop a roadmap for each of the 10 chemicals showing what steps it is taking to gather the necessary information for aggregate exposure assessment and how it will calculate or estimate the combined exposures resulting from multiple pathways or uses for the general population and potentially exposed or susceptible subpopulations.

Problem formulations should also address whether and how EPA will use "cumulative risk" methodologies for the first 10 risk evaluations. This, too, is an area that EPA has addressed in several guidance documents.[11] The Agency defines "cumulative risk" as "the combined risks from aggregate exposures (i.e., multiple route exposures) to multiple agents or stressors" and has explained that:

> "In cumulative risk assessments that examine risks posed by multiple chemicals, exposure assessments evaluate a population's chemical exposures through multiple routes of exposure over time. Such assessments may encompass multiple exposure timeframes in which the timing and intensity of exposures to different chemicals are examined relative to each other. It is also important to determine whether the exposures to multiple chemicals can lead to toxicokinetic interactions or toxicodynamic interactions. In addition to providing information about multiple chemical exposures in the general population, these exposure assessments identify potentially susceptible or vulnerable subpopulations in the study area and potentially unique pathways of exposure in those subpopulations."[12]

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[9] Exposures from TSCA-exempt uses such as personal care products or biocides should also be included in scoping documents and risk evaluations because of the need to account for their contribution to aggregate risk, even though regulatory authority over these products is not available under TSCA but derives from other laws administered by EPA or agencies such as FDA. This is now standard practice in implementing the Food Quality Protection Act (FQPA). The scoping documents contain limited and incomplete information on exposures to the listed chemicals from non-TSCA uses.

[10] https://www.epa.gov/sites/production/files/2015-07/documents/aggregate.pdf

[11] E.g., *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity.* U.S. Environmental Protection Agency, Office of Pesticide Programs, Washington, DC. (2002) Available at http://www.epa.gov/oppfead1/trac/science/cumulative_guidance.pdf; *Framework for Cumulative Risk Assessment,* U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Washington, DC. EPA/600/P-02/001F (2004). Available at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=54944.

[12] EPA National Center for Environmental Assessment, *Concepts, Methods and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures and Effects: A Resource Document,* at xxviii (August 2007).

The importance of examining risks posed by multiple chemicals with overlapping pathways of exposure and common adverse health effects was also underscored by the National Academy of Sciences (NAS) in its Phthalates and Cumulative Risk report.[13]

We recommend that, in its problem formulations, EPA should commit to perform cumulative risk assessments whenever a population or subpopulation exposed to the subject chemical is also exposed to other chemicals that have similar health effects. In this situation, total risk to the relevant population or subpopulation will be a function not just of exposure to the subject chemical in isolation but of combined exposure to that chemical and other chemicals which have additive or synergistic health effects.

A compelling case for examining cumulative risks will exist where EPA is in parallel conducting risk evaluations on multiple chemicals within a class that have similar chemical structures, conditions of use and adverse health effects. An example of such a grouping is the four solvents (TCE, PERC, MC and NMP) among the initial 10 chemicals: not only is it likely that workers and consumers are exposed to all or some of these solvents simultaneously but their common hazards (i.e. neurotoxicity, reproductive toxicity) are likely to magnify the risks of such concurrent exposures. The problem formulations for these four chemicals should recognize the need to examine the cumulative risks they present and describe how EPA will evaluate cumulative risk scenarios.

IV. ONGOING USE AND DISPOSAL OF CHEMICAL PRODUCTS THAT ARE NO LONGER BEING MANUFACTURED FALL WITHIN THE TSCA DEFINITION OF "CONDITIONS OF USE" AND MUST BE ASSESSED IN RISK EVALUATIONS

Several of the 10 chemicals – asbestos, perchloroethylene (PERC), TCE, MC, carbon tetrachloride (CTC) and hexabromocyclododecane (HBCD) – contribute to ongoing exposure and risk as a result of historical manufacturing and processing activities that have been discontinued. In many cases, the current and foreseeable risks associated with these activities are significant. Nonetheless, the scoping documents provide limited information about these risk and exposure scenarios and take the position that they are outside the scope of risk evaluations except possibly as a source of information about aggregate exposure. Each scoping document contains this statement:

> "EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. For instance, the conditions of use for purposes of section 6 might reasonably include the use of a chemical substance in insulation where the manufacture, processing or distribution in commerce for that use is prospective or on-going, but would not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical

[13] National Research Council. Committee on the Health Risks of Phthalates, Board on Environmental Studies and Toxicology, Division on Earth and Life Studies. 2008. Phthalates and cumulative risk assessment: the task ahead. Washington, D.C.: National Academies Press.

substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses."[14]

We believe that EPA is incorrectly interpreting the provisions of LCSA. The definition of "conditions of use" in section 3(4) covers the "circumstances . . . under which a chemical substance is . . . known or reasonably foreseen to be . . . used or disposed of." Where a chemical is performing an ongoing *in situ* function as a result of previous manufacturing and processing activity, that function comprises a current "use" of the chemical that is "known" to be occurring.

For example, although asbestos may no longer be sold as insulation, the asbestos insulation installed in millions of US buildings continues to perform insulating functions and thus is a current ongoing "use" of asbestos. Installed asbestos-containing building materials (ACBMs) represent one of the largest sources of asbestos accessible to the general public in the US, and the largest asbestos-exposed population consists of people who occupy buildings and homes with ACBMs. Maintenance and construction activities involving ACBMs are also frequent and widespread and account for the largest present-day increase in mesothelioma illness and death in the US.[15]

Similarly, the Healthy Building Network estimates there are 66-132 million pounds (30,000-60,000 metric tons) of HBCD in insulation in existing buildings.[16] These ongoing insulation uses are and will continue to be critical sources of ongoing exposures. HBCD is also present in cars and furniture as a flame retardant and its use in these long-lived consumer articles will contribute to ongoing exposures for years to come.[17]

Equally important, the disposal of building materials or consumer products containing asbestos or HBCD is an ongoing occurrence as buildings are torn down or remodeled and cars and furniture are replaced. Thus, the resulting releases into the environment and communities comprise a "circumstance . . . under which [these chemicals] are . . . known or reasonably foreseen to be . . . disposed of." As "conditions of use" within the TSCA definition, these activities and the risks they present are likewise required to be addressed in risk evaluations under section 6(b). For both chemicals, the immediate and long-term exposures associated with disposal of *in situ* building materials and products are likely to be widespread and significant well into the future.

To exclude from risk evaluations ongoing and future exposures from *in situ* uses of discontinued products would create a sizable gap in the life-cycle assessments of risk that Congress directed EPA to conduct under the new law. This would deprive the public, scientists and regulators of a comprehensive

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[14] EPA, *Scope of the Risk Evaluation for Asbestos*, June 2017, at 8.

[15] US CDC study, "Malignant Mesothelioma Mortality – United States 1999 to 2005."

[16] Safer Chemicals, Healthy Families et al. Comments to the U.S. Environmental Protection Agency (EPA) on the Scope of its Risk Evaluation for the TSCA Work Plan Chemicals: CYCLIC ALIPHATIC BROMIDE CLUSTER or HEXABROMOCYCLODODECANE (HBCD). March 15, 2017. https://healthybuilding.net/uploads/files/saferchemicals-hbcd.pdf

[17] For chemicals like TCE and PERC, the uses that contributed to widespread contamination of groundwater and drinking water may in fact be uses for which these chemicals are still being sold, requiring EPA to include them in its risk evaluations even under its narrow interpretation of the law.

picture of one of the largest sources of continuing and future risk. One consequence would be that EPA would lack the scientific basis to ban resumption of the sale and distribution of discontinued products containing asbestos, HBCD and similar chemicals despite the unreasonable risks that they present. In addition, decision-makers would be unable to reduce ongoing exposures and impose safeguards against unsafe disposal because they would lack a meaningful risk evaluation to inform these actions. Just as TSCA provides authority to evaluate the risks associated with ongoing exposures from discontinued activities, so it gives EPA the authority under section 6(a) to reduce these risks, yet the Agency would be stymied by the absence of a risk evaluation that provides a basis for such regulation.[18]

In short, EPA must characterize and assess ongoing exposures from the use and disposal of discontinued products and determine the risks they present as part of its risk evaluations on the initial 10 chemicals. The scoping documents provide virtually no discussion of these sources of exposure to the 10 chemicals. Nothing in the law allows EPA to exclude these risks from its evaluations. EPA must correct this omission during problem formulation.

V. OZONE DEPLETION AND GLOBAL WARMING POTENTIAL POSE ENVIRONMENTAL AND HEALTH RISKS THAT FALL WITHIN THE SCOPE OF TSCA RISK EVALUATIONS

In earlier submissions, SCHF and its members highlighted data showing the high ozone depleting potential of MC, CTC and 1-Bromopropane (1-BP).[19] The scoping documents do not address these properties of the three chemicals. Nor do they examine the global warming potential (GWP) of any of the 10 chemicals. These omissions conflict with the express purpose of risk evaluations under section 6(b)(4)(A): to "determine whether a chemical substance presents an unreasonable risk of injury to health *or the environment"* (emphasis added). They also fail to meet the Agency's obligation under section 6(b)(4)(F)(i) to "integrate and assess information . . . that is relevant to specific risks of injury to health *or the environment"* (emphasis added). Ozone depletion and global warming potential clearly pose risks to the environment and they are also recognized risk factors for human health.[20,21] Nothing in the law allows EPA to exclude these risks from its evaluations.

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[18] For some chemicals like lead and asbestos, other laws administered by EPA address handling and disposal of *in situ* materials. The Agency may be able to refer the findings of its risk evaluations to the programs implementing these laws under TSCA section 9(b) in lieu of further regulation under section 6. However, there are no existing laws that address ongoing exposure from use and disposal of discontinued products containing HBCD, perfluorinated chemicals and other substances and therefore the availability of the protections afforded under section 6 of TSCA may be critical to addressing their risks.

[19] See Comments of Safer Chemicals Healthy Families on Risk Evaluation Scoping Documents for Ten Chemical Substances under the Toxic Substances Control Act, March 15, 2017.

[20] The human health risks of ozone depletion are well recognized by the Agency and documented, at least in part, on EPA's webpage, "Health and Environmental Effects of Ozone Layer Depletion:" "Ozone layer depletion increases the amount of UVB that reaches the Earth's surface. Laboratory and epidemiological studies demonstrate that UVB causes non-melanoma skin cancer and plays a major role in malignant melanoma development. In addition, UVB has been linked to the development of cataracts, a clouding of the eye's lens." https://www.epa.gov/ozone-layer-protection/health-and-environmental-effects-ozone-layer-depletion (Accessed 9-18-17)

[21] The human health risks of global warming were well recognized and documented, at least in part, by the agency prior to the arrival of Administrator Pruitt, as outlined in the legacy pages at: https://19january2017snapshot.epa.gov/climate-impacts/climate-impacts-human-health_.html While that page is being updated, "...to reflect EPA's priorities under the leadership of President Trump and Administrator Pruitt," the Agency still notes, "Climate change is having direct and indirect impacts on the health of people. More extreme

The EPA Office of Air and Radiation (OAR) has considerable expertise in both ozone depletion and global warming and has assessed some (but not all) of the 10 chemicals from the perspective of these concerns. OAR can help OCSPP draw on this prior work for its TSCA risk evaluations and perform new assessments for those chemicals whose ozone depletion and global warming impacts have not previously been examined. By addressing these impacts in TSCA risk evaluations, EPA will fulfill the law's goal of providing a comprehensive picture of environmental and health risks across the chemical's life cycle. In particular cases, it may also highlight contributors to ozone depletion and global warming that have been overlooked and may warrant restriction. Whether these impacts can be adequately addressed under the Clean Air Act (CAA) or under TSCA need not be determined in the risk evaluation itself and can be deferred to the later evaluation of risk management options under section 6(a).

VI. EPA RISK EVALUATIONS SHOULD NOT REASSESS USES OF TCE, MC AND NMP THAT WERE FULLY ASSESSED IN ITS PROPOSED SECTION 6(a) RULES

EPA has proposed to ban certain uses of TCE, MC and NMP under section 6(a) of amended TSCA.[22] As the basis for these proposed rules, EPA conducted comprehensive exposure and risk assessments on the targeted uses of the three chemicals. These assessments were subject to public comment and peer review both during their development and again as part of the rulemaking process.

In its scoping documents for the three chemicals, EPA indicates that it intends to rely on the completed assessments and will not "reassess" the targeted uses.[23] We strongly agree with this approach. It would be counterproductive for the Agency reopen these assessments for yet another round of public input and to redo the extensive analysis they contain simply so industry commenters can have another bite at the apple on findings they dislike. Moreover, we believe that the next step in the rulemakings is for EPA to issue final rules as quickly as possible. These rules, once issued, should close the book on the targeted uses and enable EPA to focus its risk evaluations on uses that have not yet been assessed. In its more comprehensive risk evaluations, however, EPA should incorporate its earlier assessments so that the exposures they describe can be accounted for in determining aggregate exposure to the three chemicals.

VII. EPA SHOULD NOT REVISIT DEFINITIVE FINDINGS IN IRIS ASSESSMENTS, WHICH REPRESENT THE AGENCY'S AUTHORITATIVE PEER-REVIEWED DETERMINATIONS OF THE HEALTH EFFECTS OF CHEMICALS

Five of the 10 chemicals – TCE, MC, CTC, PERC and 1,4-dioxane – have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect

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weather events, heat waves, spread of infectious diseases and detrimental impacts on air and water quality are having impacts on our health." https://www.epa.gov/climate-research/human-health-and-climate-change-research (accessed 9-18-17).

[22] Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing under TSCA Section 6(a), 82 Fed. Reg. 7432 (Jan. 19, 2017); Trichloroethylene; Regulation of Certain Uses under TSCA § 6(a), 81 Fed. Reg. 91592 (Dec. 16, 2016) and Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses under TSCA Section 6(a), 82 Fed. Reg. 7464 (Jan. 19, 2017).

[23] See, e.g., EPA. *Scope of the Risk Evaluation for Trichloroethylene,* June 2017, at 33.

years of work by EPA scientists, multiple rounds of public comment, inter and intra-agency consultation, and extensive peer review, often by the Agency's independent Science Advisory Board (SAB) or the National Academy of Sciences (NAS).

Where EPA is conducting a TSCA risk evaluation of a chemical that has already been assessed under IRIS, the conclusions of the IRIS assessment should be presumed to be applicable to the TSCA evaluation as a definitive statement by the Agency of the best available science. To revisit IRIS findings would be inefficient and resource-intensive at a time when the Agency is struggling with workforce and budget reductions. It would also make the three-year statutory deadline for completing risk evaluations even more challenging by greatly expanding the scope of EPA's work effort. Most significantly, reopening IRIS findings would prolong scientific uncertainty on issues that have been addressed and resolved through an authoritative, transparent and inclusive EPA process. Like other Agency actions, IRIS assessments often give rise to differences of opinion and some stakeholders may be disappointed by the outcome. But this does not mean that EPA should reinvent the wheel and provide another bite at the apple on scientific determinations that have been made after thorough deliberation and a robust process.

In sum, the problem formulation documents on the 10 chemicals should make clear that EPA's risk evaluations will rely on previous IRIS assessments in determining health effects that those assessments address.

VIII. IN EVALUATING WORKPLACE RISKS, EPA SHOULD RECOGNIZE THE UNEVEN USE AND EFFECTIVENESS OF ENGINEERING CONTROLS, LABELING AND PERSONAL PROTECTIVE EQUIPMENT IN PREVENTING OCCUPATIONAL EXPOSURE

Several scoping documents indicate that, in its approach to occupational exposure analysis, EPA will "[c]onsider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios."[24] These measures are certainly relevant factors in analyzing occupational exposures. However, it is essential that EPA not presume that they will be effective in preventing exposure in all workplaces and for all employees. In many cases, they may in fact provide limited protection, particularly for short-term poorly trained workers in small shops and workers whose English language skills are challenged.

In its proposed section 6(a) rules for TCE, MC and NMP, EPA explained at some length why label warnings and instructions are not uniformly read, comprehended or followed and thus provide limited protection. This was not a mere opinion on EPA's part but the result of an examination of nearly fifty studies.[25] Based on this review, EPA's conclusions as described in its initial TCE rulemaking were as follows:

> "The Agency determined that warning labels and instructions alone could not mitigate the risks to the extent necessary so that TCE no longer presents the identified unreasonable risks to users. The Agency based this determination on an analysis of 48 relevant studies or meta-analyses, which found that consumers and professionals do not consistently pay attention to

[24] See, for example, US EPA (2017). Scope of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster. Pg. 45

[25] OPPT summarized these studies in a paper entitled *The Effectiveness of Labeling on Hazardous Chemicals and Other Products* (March 2016)(Ref. 33 in rulemaking docket).

labels; consumers and professional users often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies."[26]

In the TCE vapor degreasing proposal, EPA further concluded that comprehension of warnings would be unusually challenging because of the complexity of the information conveyed:

> "EPA found that presenting information about TCE on a label would not adequately address the identified unreasonable risks because the nature of the information the user would need to read, understand, and act upon is extremely complex. It would be challenging to most users to follow or convey the complex product label instructions required to explain how to reduce exposures to the extremely low levels needed to minimize the risk from TCE. Rather than a simple message, the label would need to explain a variety of inter-related factors, including but not limited to the use of local exhaust ventilation, respirators and assigned protection factor for the user and bystanders, and time periods during pregnancy with susceptibility of the developing fetus to acute developmental effects, as well as effects to bystanders. *It is unlikely that label language changes for this use will result in widespread, consistent, and successful adoption of risk reduction measures by users and owners.*[27]

Similarly, EPA cautioned that "there are many documented limitations to successful implementation of respirators", including these well-known problems: [28]

> "Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-face piece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good face piece fit, including those individuals whose beards or sideburns interfere with the face piece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, January 8, 1998). According to OSHA, 'improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health. (63 FR 1189-1190).'"

EPA based these conclusions on expert analyses by OSHA, which has extensive experience with respirators under its workplace standards.

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[26] 81 FR at 91601.
[27] 82 FR 7441 (emphasis added)
[28] 82 FR 7445

The problem formulation documents should explicitly recognize that industrial hygiene controls do not necessarily provide reliable and effective protection from exposure and that the adequacy of these controls needs to be examined on a case-by-case basis in the context of the specific establishments where the chemical is used, the makeup of the worker population in these establishments and the diligence of employers in implementing workplace controls. During problem formulation, EPA should elaborate on how these considerations will be applied for the 10 chemicals.

More generally, when considering occupational exposures, EPA needs to recognize and account for differences in levels of exposure, workplace practices and susceptibility that result in significant gradations in risk, even within a single workplace. In workplaces where chemicals and chemical products are used, exposures typically occur most intensely among a highly exposed subgroup, rather than uniformly across the population of workers. In a vehicle repair shop, for example, chemical-intensive tasks on brakes, engines, and drive-train components are performed by a subset of workers who experience high levels of exposure to aerosolized degreasing solvents, whereas other workers in the same shop who perform diagnostic or electrical work, for example, experience little or no exposure to these solvents. To effectively characterize the "conditions of use" among workers, EPA must account for the levels and duration of exposure—and therefore risk—that occurs within highly exposed subgroups as a consequence of actual workplace conditions, rather than relying on an "average" estimated exposure across a population of workers, based on an assumption of "intended" use.

IX. EPA SHOULD NOT EXCLUDE FROM THE 1,4-DIOXANE EVALUATION ITS PRODUCTION AS A BYPRODUCT OR IMPURITY, WHICH IS A SIGNIFICANT SOURCE OF CONTAMINATION OF WATER SOURCES

The scoping document for 1,4-dioxane takes the unusual approach of precluding any consideration of this substance's manufacture as a byproduct or impurity in EPA's risk evaluation:

> "In the case of 1,4-dioxane, EPA anticipates that production of 1,4-dioxane as a by-product from ethoxylation of other chemicals and presence as a contaminant in industrial, commercial and consumer products will be excluded from the scope of the risk evaluation. These 1,4-dioxane activities will be considered in the scope of the risk evaluation for ethoxylated chemicals. EPA believes its regulatory tools under TSCA section 6(a) are better suited to addressing any unreasonable risks that might arise from these activities through regulation of the activities that generate 1,4-dioxane as an impurity or cause it to be present as a contaminant than they are to addressing them through direct regulation of 1,4-dioxane"[29]

This is a deeply flawed approach that will weaken the 1,4-dioxane risk evaluation and result in inadequate risk reduction during any subsequent rulemaking under section 6(a).

1,4-dioxane is a probable carcinogen that has contaminated drinking water and groundwater in multiple parts of the country, eliciting expressions of concern from many public officials and communities. A recent analysis of data from EPA-mandated monitoring indicates that water supplies for more than 7

[29] Scope of the Risk Evaluation for 1,4-Dioxane, at 8 (June 2017)

million Americans in 27 states contain 1,4-dioxane at levels above those that EPA and other agencies believe present an acceptable cancer risk.[30]

1,4-dioxane's presence in drinking water and groundwater is linked to several pathways of release into the environment. In addition to its manufacture as a chemical product, 1,4-dioxane is a byproduct of plastic production and other chemical manufacturing processes utilizing ethoxylation. Due to its production as a byproduct, it is present as an impurity in several industrial, commercial and consumer products. 1,4-dioxane often is found in the wastewater discharged by industrial facilities and POTWs. Its presence in wastewater is likely attributable not only to intentional production and use activities but to the use and disposal of products in which it is present as an impurity.

If 1,4-dioxane's manufacture as a byproduct and presence in products and waste streams as an impurity are excluded from EPA's risk evaluation, it will have no basis for accounting for these sources of environmental release and will be unable to characterize their contribution to levels of the chemical found in drinking water, surface water and ground water. This will make its assessment of the extent and causes of water contamination incomplete and undermine its ability to conduct an informed evaluation of the options for reducing contamination and risk. Any action it later decides to take under section 6 will thus be based on inadequate information and analysis and, as a result, may be ineffective and under-protective.

Manufacture as a byproduct is plainly within the definition of "conditions of use" in section 3(4) of TSCA. There is no basis in this provision or other parts of the law for differentiating between manufacture as a byproduct and purposeful production and including one in a risk evaluation but excluding the other. And in this instance, there's no evidence (and EPA does not claim) that exposure to and release of 1,4-dioxane as a byproduct and impurity are inconsequential from a risk standpoint.[31]

While EPA suggests that it might be more efficient or effective to address byproduct production of 1,4-dioxane in a separate section 6(a) rulemaking for ethoxylated chemicals, this seems far-fetched. If EPA assesses the contribution of these chemicals to 1,4-dioxane water contamination in the current risk evaluation, it will have a sound basis to regulate their production and use under section 6(a) if they are found to present an unreasonable risk of injury.[32] Otherwise, there is no telling when EPA might mitigate water contamination resulting from byproduct production of 1,4-dioxane production. Thus far, EPA has offered no indication when, if ever, it will make a high-priority designation for ethoxylated chemicals and assess their contribution to the presence of 1,4-dioxane in the environment.

We recommend that during problem formulation, EPA add 1,4-dioxane production as a byproduct and impurity to the scope of its risk evaluation.

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[30] Environmental Working Group, HIDDEN CARCINOGEN TAINTS TAP WATER, CONSUMER PRODUCTS NATIONWIDE (September 2017).

[31] Under our interpretation of section 6(b), EPA could not exclude a condition of use from the risk evaluation scope based on low risk in any event.

[32] Section 6(a) does not limit EPA to regulating purposeful production of a chemical subject to a risk evaluation. It can regulate production by other means so long as it has been assessed in that evaluation and found to present an unreasonable risk.

X. BASED ON THE GENERAL PRINCIPLES OUTLINED ABOVE AND OTHER GAPS IN ITS SCOPING DOCUMENTS, EPA SHOULD AUGMENT THESE DOCUMENTS IN SEVERAL SPECIFIC RESPECTS DURING PROBLEM FORMULATION

Applying the general approaches outlined in these comments and in light of several omissions we identified in individual scoping documents, we recommend that EPA bolster those documents during problem formulation as follows:

1-Bromopropane (nPB)

- In our initial comments to EPA, we specifically identified nPB as being imported by companies whose primary business is supplying the cosmetics industry.[33] While the EPA has noted that authorities such as the State of California have included nPB on lists of chemicals banned in cosmetics, the potential for nPB directly or indirectly (through residues remaining from cleaning manufacturing equipment) to be present in cosmetic products is not addressed as a potential use for further assessment.
- As discussed in detail in Part V of these comments, EPA failed to address the ozone depletion potential of nPB.
- While the scoping document includes references to those exposed to nPB from use of the chemical in consumer products, as well as those co-located with dry cleaning facilities utilizing the chemical, it does not clearly identify people who may be further exposed from chemical residuals, such as those wearing clothing cleaned with nPB or their children. This pathway is not discussed, even though the scoping document for PERC includes it from the similar use of PERC in dry cleaning.

Asbestos

- EPA's scoping document claims that public comments were not received on various imported asbestos containing products available in the United States: "Products available from several online retailers and distributers include brake blocks, aftermarket friction products, roof and non-roof coatings, and gaskets, most of which are imported. No public comments were received regarding these uses." However, we submitted detailed comments highlighting all of these items and more, including other building products. [34]
- EPA's failure to include a lengthy list of legacy uses, as further discussed in Part IV of these comments, is especially problematic for asbestos which was extensively sold and distributed and remains widely present and in use in our buildings and cities.
- The recycling of legacy materials, notably asphalt shingles containing asbestos, is a unique and ongoing use of the substance, and in particular is worthy of additional consideration by the EPA, as discussed in our initial comments.[35]

[33] EPA-HQ-OPPT-2016-0741-0027 at PDF Pages 25, 27, 31.
[34] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 19, 25-27
[35] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 21-22

- There is evidence that asbestos has been present in significant levels in some talc products as the result of colocation of asbestos and talc deposits, as we discussed in our initial comments.[36] This use and ongoing exposure are not addressed in the scoping document.

- The scoping document fails to look at the risks of exposure to those who are upstream to the process of utilizing asbestos in chlor-alkali processing. This would include miners and packaging workers (who, while likely abroad, are still being exposed as a result of the substance's uses in the US considered by the EPA), as well as transportation workers, first responders, and community members who may be exposed in the shipment and transfer of asbestos to the chlor-alkali facilities.

- The absence in the scoping document of total import volumes for asbestos is troubling because it deprives the public of an understanding of the aggregate quantities of asbestos present in the US. In fact, the Asbestos Disease Awareness Organization, along with the Environmental Working Group, released a statement on September 19 that, based on data from the Department of Commerce and US International Trade Commission, 705 metric tons of raw asbestos were imported in 2016, compared to 343 metric tons in 2015. This significant increase in imports is important information that should be given prominence in the problem formulation document for asbestos.

Carbon Tetrachloride (CTC)

- As discussed in detail in Part V of these comments, EPA failed to address the ozone depletion potential and global warming potential of CTC in its scoping document. This is particularly problematic for CTC, as its use as a feedstock or intermediary was exempted from the Montreal Protocol on the false assumption that CTC production would be phased out. In actuality, CTC production is poised for an increase due to its use in HFO manufacture, as we discussed on our initial comments.[37]

- As discussed in detail in Part III of these comments, EPA failed to describe with any specificity how it will look at aggregate and cumulative exposures. In the CTC scoping document, EPA seems to specifically discredit the need for this consideration. The Agency highlights the fact that some individuals may be exposed to CTC through vapor intrusion of ground sources of CTC into their home, but then states that, ". . . this route is not likely to be significant given the agency's identified conditions of use . . ." Clearly, whether the CTC inhaled by a resident is from the vapor intrusion or from an adhesive product, they face potential health risks from it. The Agency must consider all uses and sources of exposure in the risk evaluation in order to accurately assess the human health risk and fulfill its statutory obligations.

Cyclic Aliphatic Bromides Cluster (HBCD)

- As detailed in Part IV of these comments, EPA must not exclude the ongoing use and disposal from past introduction of HBCD in a variety of products. Significant exposures will continue to occur as products incorporating HBCD move through their lifecycle, and these exposures must be considered in the risk evaluation.

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[36] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 18-19

[37] EPA-HQ-OPPT-2016-0733-0023 at PDF pages 4-5, 19

N-Methylpyrrolidone (NMP)

- As we documented in our initial comments to the EPA, NMP has been used in the manufacturing of coating for the insides of aluminum spray cans.[38] Even products not including deliberate addition of NMP may therefore be contaminated with NMP, and this exposure pathway should be considered by the Agency.

- As detailed in Part II of these comments, EPA failed to provide specifics on susceptible subpopulations. While the Agency acknowledges that reproductive effects are to be assessed, considering the well-documented reproductive toxicity of NMP, the Agency needs to better detail how the risks to women of childbearing age will be addressed.

Methylene Chloride (MC)

- While the scoping document includes a use categorization for "other consumer products" including novelty "Drinking Bird" items, we identified an additional item,[39] a "Novelty Christmas Bubbling Night Light" labeled as containing MC but not previously included in EPA's "Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Methylene Chloride." These consumer-oriented uses that are attractive to children illustrate the need to be comprehensive in the determination of "reasonably foreseeable" uses.

XI. EPA MAY NOT PREJUDGE THE ABSENCE OF ADVERSE EFFECTS FOR PARTICULAR END-POINTS AT THE SCOPING STAGE AND SHOULD DEFER SUCH CONCLUSIONS UNTIL THE SYSTEMATIC REVIEW STAGE OF ITS RISK EVALUATION

In some scoping documents, EPA has decided that the subject chemical does not raise concerns for particular endpoints and, therefore, it will not address these end-points in its risk evaluation. Examples are given in the table below where EPA concludes that HBCD, NMP and pigment violet 29 are not genotoxic:

Chemical	Example Text from EPA Scoping Document
HBCD	"Available data suggest that HBCD is not genotoxic. Existing assessments have also concluded, based on genotoxicity information and a limited lifetime study, that HBCD is not carcinogenic (NICNAS, 2012; EINECS, 2008; TemaNord, 2008; OECD, 2007). Unless new information indicates otherwise, EPA does not expect to conduct additional in-depth analysis of genotoxicity or cancer hazards in the risk evaluation of HBCD at this time."[40]
NMP	"NMP is not mutagenic, based on results from bacterial and mammalian *in vitro* tests and *in vivo* systems and is not considered to be carcinogenic (RIVM, 2013; OECD, 2007; WHO, 2001). Unless new information indicates otherwise, EPA does not expect to conduct additional in-depth analysis of genotoxicity and cancer hazards in the NMP risk evaluation."[41]

[38] EPA-HQ-OPPT-2016-0743-0031 at PDF page 18
[39] https://www.amazon.com/Bubble-Nightlight-Novelty-Christmas-Bubbling/dp/B00PV61HXC/
[40] EPA, *Scope of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster, June 2017, at.* 36
[41] EPA, *Scope of the Risk Evaluation for N-Methylpyrrolidone,* June 2017, *at* 36

Pigment violet 29	"Testing for carcinogenicity of Pigment Violet 29 has not been conducted. However, negative genotoxicity results, structure-activity considerations and the expectation of negligible absorption and uptake of Pigment Violet 29 (based on very low solubility), indicate carcinogenicity of Pigment Violet 29 is unlikely. Unless new information indicates otherwise, EPA does not expect to conduct additional, in-depth analyses of genotoxicity and cancer hazards in the risk evaluation of Pigment Violet 29."[42]

EPA cannot reach such definitive conclusions at the scoping stage. The required course under the law is to proceed with a systematic review of the relevant data (a process that EPA strongly endorses) and withhold any conclusions about particular end-points until this review is complete.

In the case of HBCD, for example, a more thorough review would reveal two recent studies indicating carcinogenic potential. One suggests that HBCD could "enhance progression of prostate cancer by modulating growth and migration of LNCaP prostate cells,"[43] and the other concludes the genotoxicity of HBCD is dose-dependent and related to DNA repair.[44] These new studies are examples of the need for EPA to assure that it has fully considered all the available data through the systematic review process in order to avoid premature and possibly incorrect decisions to drop particular end-points at the scoping stage.

XII. PROBLEM FORMULATIONS SHOULD HIGHLIGHT ASPECTS OF USE AND EXPOSURE WHERE AVAILABLE INFORMATION IS INSUFFICIENT AND REQUEST OR REQUIRE SUBMISSION OF THIS INFORMATION BY INDUSTRY

Our own research on the 10 chemicals and the scoping documents themselves confirm that there are significant gaps in the use and exposure information available to EPA and that they will weaken the quality of EPA's risk evaluations unless filled. Although the timeframe for completing risk evaluations is compressed, there is still a window for augmenting the information-base used to conduct them. To take advantage of this opportunity, EPA should include in each problem formulation document a description of information on use and exposure that is lacking and a request that industry and other interested parties submit or obtain that information as expeditiously as possible.

EPA should also signal its readiness to use its mandatory information collection authorities under TSCA to fill data-gaps where voluntary submissions are not timely or adequate. The LCSA expands these authorities and streamlines the process for exercising them, removing the barriers to information development that hamstrung EPA under the old law. For example, section 4 now authorizes EPA to issue orders where necessary to "perform a risk evaluation." Such orders can be used to require industry to develop new information on the frequency, levels and duration of exposure for a chemical's conditions of use. Alternatively, EPA can use its subpoena authority under section 11 to obtain such information that already exists but has not been provided to EPA. EPA should specify in the problem formulation document its roadmap and timetable for filling data gaps using these authorities.

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[42] EPA, *Scope of the Risk Evaluation for Pigment Violet 29*, June 2017, at 29.

[43] Seung-Hee Kim, et al, 2016. Influence of hexabromocyclododecane and 4-nonylphenol on the regulation of cell growth, apoptosis and migration in prostatic cancer cells. Toxicology in Vitro. 32:240-247. April 2016.

[44] Rui Jing Li, et al. Hexabromocyclododecane-induced Genotoxicity in Cultured Human Breast Cells through DNA Damage. Letter to Editor. Biomedical and Environmental Sciences. 30(4): 296-300.

Where the database available for a risk evaluation is incomplete, it is critically important that EPA not equate the absence of data with the absence of risk. For example, if EPA lacks data to assess a chemical's carcinogenicity, its risk evaluation needs to clearly state that cancer risk has not been addressed, that the chemical may or may not present such a risk, and that this end-point is outside the scope of its evaluation because of the absence of data. EPA should make the same disclaimers for conditions of use that cannot be adequately characterized, even by using default assumptions or extrapolation methods, because basic information about the nature of the use and scope and extent of exposure is unavailable.

XIII. EPA NEEDS TO LIMIT REDACTION FROM SCOPING AND PROBLEM FORMULATION DOCUMENTS OF CRITICAL INFORMATION CLAIMED CBI SO THAT TRANSPARENCY AND PUBLIC PARTICIPATION IN THE RISK EVALUATION PROCESS ARE NOT IMPAIRED

The scoping documents omit critical exposure and use information that has been claimed as confidential business information (CBI) that must be withheld from disclosure under TSCA. In some cases, the information is as basic as the total volume of the chemical manufactured and imported in the US. For example, the scoping documents fail to provide total manufacture/import volumes for asbestos, HBCD and pigment violet 29. Not only is this information obtainable in the public domain but it is fundamental to public understanding of the risks posed by these chemicals and, therefore, to informed public participation in the risk evaluation process.[45]

During problem formulation, EPA should make a concerted effort to limit the redaction of CBI-claimed production, use and exposure data that are essential for the transparency of the risk evaluation process. Several tools can be used for this purpose.

First, section 14(b)(3) of TSCA declares that "information not protected from disclosure" includes:

> "any general information describing the manufacturing volumes, expressed as specific aggregated volumes or . . . expressed in ranges."
>
> "a general description of a process used in the manufacture or processing and industrial, commercial or consumer functions and uses of a chemical, substance, mixture or article containing a chemical substance or mixture . . ."

This provision compels the disclosure of much of the information in scoping documents claimed CBI.

Alternatively, section 14(d)(7) provides that the Administrator may disclose information otherwise warranting CBI protection if he or she "determines that disclosure is relevant in a proceeding under this Act." The risk evaluations that EPA is conducting on the 10 chemicals under section 6(b)(2)(A) of TSCA represent a "proceeding" under TSCA. Information submitted by industry on the 10 chemicals is plainly "relevant" to these evaluations because it will inform how EPA assesses exposures and related risks

[45] For asbestos, SCHF and Environmental Health Strategy Center were able to use US government data accessible through the Panjiva database to determine annual asbestos imports over an extended period. As noted above, a more recent analysis of import data by the Asbestos Disease Awareness Organization shows that asbestos imports doubled in 2016, a startling finding that should be central to EPA's risk evaluation because of its implications for exposure to asbestos in the US.

associated with manufacture, processing and downstream commercial and consumer use. Thus, EPA can and should decide to disclose all information on the 10 chemicals notwithstanding any CBI claims.

Finally, to the extent these grounds for disclosure do not apply, EPA should use its authority under section 14(f)(1)(C) to require immediate substantiation of CBI claims for information for which "disclosure would be important to assist the Administrator in conducting risk evaluations . . . under section 6." This provision should be applied broadly to accomplish disclosure of all information that would be of value to the public in commenting on risk evaluations.

CONCLUSION

Our groups appreciate the opportunity to comment on the 10 scoping documents and look forward to continued dialogue with the Agency as it develops problem formulation documents and proceeds with risk evaluations on the 10 chemicals.

If you have any questions, please contact SCHF counsel, Bob Sussman, at Ex. 6 Personal Privacy (PP)@comcast.net or Ex. 6 Personal Privacy (PP)

Respectfully submitted,

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September 19, 2017

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments of Safer Chemicals Healthy Families on Risk Evaluation Scoping Documents for Ten Chemical Substances under the Toxic Substances Control Act

Submitted via Regulations.gov (September 19, 2017)

1,4-Dioxane. Docket ID No.: EPA-HQ-OPPT-2016-0723.

1-Bromopropane. Docket ID No.: EPA-HQ-OPPT-2016-0741.

Asbestos. Docket ID No.: EPA-HQ-OPPT-2016-0736.

Carbon Tetrachloride. Docket ID No.: EPA-HQ-OPPT-2016-0733.

Cyclic Aliphatic Bromide Cluster (Hexabromocyclododecane or HBCD). Docket ID No.: EPA-HQ-OPPT-2016-0735.

Methylene Chloride. Docket ID No.: EPA-HQ-OPPT-2016-0742.

N-Methylpyrrolidone (NMP). Docket ID No.: EPA-HQ-OPPT-2016-0743.

Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f]diisoquinoline-1,3,8,10(2H,9H)-tetrone). Docket ID No.: EPA-HQ-OPPT-2016-0725.

Trichloroethylene (TCE). Docket ID No.: EPA-HQ-OPPT-2016-0737.

Tetrachloroethylene (also known as Perchloroethylene). Docket ID No.: EPA-HQ-OPPT-2016-0732.

INTRODUCTION AND SUMMARY

Safer Chemicals, Health Families (SCHF), Earthjustice, Natural Resources Defense Council (NRDC), Environmental Health Strategy Center, Toxic-Free Future and Asbestos Disease Awareness Organization (ADAO) submit these comments on the scoping documents developed by the Environmental Protection Agency (EPA) on the initial 10 chemicals selected for risk evaluations under the newly enacted Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). These organizations are committed to enhancing the safety of chemicals used in homes, workplaces and products and strongly support effective and health-protective implementation of the LCSA.

Through LCSA, Congress amended the Toxic Substances Control Act (TSCA) to establish a new framework for conducting timely, comprehensive and science-based risk evaluations for chemicals of concern. The law provides that EPA's evaluations must be strictly risk-based and must result in a definitive determination of whether the evaluated substance as a whole presents an unreasonable risk of injury to health and the environment across its life cycle, without regard to cost and other non-risk factors.

Congress wanted EPA to launch the risk evaluation process expeditiously. Accordingly, in section 6(b)(2)(A) of TSCA, it directed EPA to assure that evaluations are initiated within six months of the law's enactment on 10 substances drawn from the 2014 TSCA Workplan list. EPA designated these 10 substances on December 19, 2016,[1] and following a public meeting and comment period, released draft scoping documents on June 22. Soon thereafter, EPA announced that it was developing problem formulation documents on the 10 chemicals and would release them for further comment by the end of the year. It also requested comments on the scoping documents in order to inform its approach to problem formulation.[2]

These comments address general issues common to the 10 chemicals as well as several chemical-specific issues. We are submitting our comments to all ten of the EPA dockets. The comments build on earlier submissions by these groups, including our March 15 comments on the scoping process and our July 24 letter to the Agency providing initial reactions to the 10 scoping documents. We have coordinated with a number of other public health and scientific organizations in developing comments on the scoping documents and generally support their recommendations.

The main messages and key recommendations in our comments are as follows:

- Problem formulation can fill gaps in scoping documents and enhance their depth of analysis but cannot be used to remove uses, exposures and hazards from the risk evaluation scope
- EPA should use problem formulation to provide more detail on the potentially exposed and susceptible subpopulations it will consider and how risks to these subpopulations will be determined
- Problem formulations should also describe EPA's strategies for assessing risks from aggregate and cumulative exposures
- Ongoing use and disposal of chemical products that are no longer being manufactured fall within the TSCA definition of "conditions of use" and must be included in problem formulations and assessed in risk evaluations
- Chemicals with ozone depletion and global warming potential pose environmental and health risks that fall within the scope of TSCA risk evaluations
- EPA risk evaluations should not reassess uses of trichloroethylene (TCE), methylene chloride (MC) and N-Methylpyrrolidone (NMP) that were fully assessed in its proposed section 6(a) rules, although these exposure pathways should be included in its determinations of aggregate exposure to these chemicals
- In the course of TSCA risk evaluations, EPA should not revisit definitive findings in IRIS assessments since these assessments represent the Agency's authoritative, peer reviewed determinations on the health effects of the chemicals they address
- In evaluating workplace risks, EPA should recognize and account for the uneven use and effectiveness of engineering controls, labeling and personal protective equipment in preventing occupational exposure and determine risks to workers in situations where these measures are not in place or ineffective
- EPA should not exclude from the 1,4-dioxane evaluation its production as a byproduct or impurity, which is a significant source of contamination of water sources and cancer risk

[1] 81 Federal Register 91927
[2] 82 Fed. Reg. 31,592 (July 7, 2017).

- In order to apply these general principles and fill other gaps in its scoping documents, these documents must be expanded and strengthened in several specific respects during problem formulation
- EPA should not prejudge the absence of adverse effects for particular end-points at the scoping stage but should defer such conclusions until the systematic review phase of its risk evaluation as the law requires
- Problem formulations should highlight aspects of use and exposure where available information is insufficient and request or require submission of this information by industry and other interested parties
- EPA needs to take stronger steps to limit CBI treatment of critical information during the risk evaluation process so that transparency and public participation in that process are not impaired

I. PROBLEM FORMULATION CAN FILL GAPS IN SCOPING DOCUMENTS AND ENHANCE THEIR DEPTH OF ANALYSIS BUT CANNOT BE USED TO REMOVE USES, EXPOSURES AND HAZARDS FROM THE RISK EVALUATION SCOPE

The 10 chemicals undergoing risk evaluations have widespread and substantial exposure and multiple adverse health effects. Comprehensive and health protective assessments of their safety are essential to safeguard communities and vulnerable populations and to set a precedent for strong and effective implementation of the new law. For this reason, our groups made a significant investment in characterizing the use and exposure profiles of several of the 10 chemicals and provided extensive submissions to the Agency to help inform its scoping documents for these chemicals.

The scoping documents represent a considerable amount of work in a short period of time and provide a helpful starting point for the 10 evaluations. However, the July 7 Federal Register notice announcing the availability of the scoping documents acknowledges that the Agency was unable to process all the information gathered during the scoping process and that the scoping documents were not as "refined or specific" as EPA had hoped. We agree with this assessment and believe that the scoping documents contain serious gaps, lack sufficient information on use and exposure, impose questionable limitations on the risk scenarios to be examined and fail to provide a roadmap to key elements of assessment methodology. These shortcomings reduce the utility of the scoping documents in laying the groundwork for well-informed and rigorous risk evaluations.

Given their limitations, we believe that expanding and strengthening the scoping documents through a problem formulation process is appropriate in this instance. However, neither LCSA nor the recently promulgated risk evaluation process rule refers to or authorizes problem formulation. Because it has no basis in the law, we oppose using problem formulation to narrow the scope of risk evaluations by deleting conditions of use, exposure pathways or health or environmental end-points identified in the June scoping documents. Section 6(b)(4)(D) of amended TSCA provides that, "not later than 6 months after the initiation of a risk evaluation," EPA must "publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and the potentially exposed or susceptible subpopulations the Administrator expects to consider." EPA met this requirement in its June scoping documents. The law provides no basis for EPA to remove uses, hazards or exposures from a risk

evaluation after its scope has been established in accordance with section 6(b)(4)(D).[3] Since problem formulation is not a recognized step in the risk evaluation process or a substitute for scoping under LCSA, it cannot be used narrow a risk evaluation's scope after-the-fact.

We do support, however, using problem formulation to provide more detail on the conditions of use, potentially exposed and susceptible subpopulations, and exposure pathways that EPA will evaluate as well as further explanation of the methodologies that EPA will use in its analysis of these and other risk assessment elements. This will help better structure the risk evaluations, assure that all relevant information is considered, and characterize more fully the conditions of use to be evaluated – without narrowing the risk evaluation scope.

II. EPA SHOULD USE PROBLEM FORMULATION TO PROVIDE MORE DETAIL ON THE POTENTIALLY EXPOSED AND SUSCEPTIBLE SUBPOPULATIONS IT WILL CONSIDER AND HOW RISKS TO THESE SUBPOPULATIONS WILL BE DETERMINED

One area that would benefit from greater elaboration during problem formulation is the identification of potentially exposed or susceptible subpopulations that require consideration in risk evaluations under TSCA section 6(b)(4)(F). The scoping documents provide nearly identical general "boilerplate" descriptions of such subpopulations. Further particulars on the size, geographic location, demographic characteristics and exposure profile of each subpopulation EPA has identified would provide helpful assurance that the risks to that subpopulation will be characterized with the rigor that TSCA requires.

It is also critical for EPA to spell out the methodology it intends to use to determine the nature and magnitude of the risks that chemicals pose to each subpopulation. Such subpopulations are often comprised of low income and/or people of color and exposed to a disproportionate share of pollution, environmental hazards, and social and economic stressors. Multiple exposures to chemical and non-chemical stressors collectively increase the risk of harm, combined with synergistic effects with other health stressors such as limited access to quality health care.[4,5] EPA's risk evaluations need to fully account for these factors and its problem formulations should explain how it intends to do so.

In regard to greater susceptibility, the following are well-known factors that increase biologic sensitivity or reduce resilience to exposures,[6,7] and should be considered consistently for all 10 chemicals to identify susceptible subpopulations:

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[3] EPA's final risk evaluation rule, in contrast to its proposal, would permit the Agency to select which conditions of use to include in risk evaluation scopes as opposed to including all such uses. 82 Fed. Reg. 33,726 (July 20, 2017). Our groups argued in their comments on the proposal that the law required the Agency to address all conditions of use in its risk evaluations, as was recognized in the Agency's original proposal. Along with several other groups, we are challenging EPA's contrary interpretation in its petition for judicial review of the risk evaluation rule. Regardless of the outcome of this challenge, we believe that EPA has no basis to narrow the risk evaluation to exclude conditions of use once they have been included in its scope.

[4] Morello-Frosch R, Zuk M, Jerrett M, Shamasunder B, Kyle AD. Understanding the cumulative impacts of inequalities in environmental health: Implications for policy. Health Aff. 2011;30(5):879–87.

[5] Vesterinen HM, Morello-Frosch R, Sen S, Zeise L, Woodruff TJ. Cumulative effects of prenatal-exposure to exogenous chemicals and psychosocial stress on fetal growth: Systematic-review of the human and animal evidence. Meliker J, editor. PLoS One. 2017 Jul 12;12(7):e0176331.

[6] Morello-Frosch R, Zuk M, Jerrett M, Shamasunder B, Kyle AD. Understanding the cumulative impacts of inequalities in environmental health: Implications for policy. Health Aff. 2011;30(5):879–87.

Intrinsic/ endogenous factors

- Genetic polymorphisms/ genetics/ genetic makeup
- Health status/ nutritional status/ disease status/ pre-existing conditions
- Prenatal life stage
- Age

Extrinsic factors

- Multiple exposures/ co-exposures
- Race/ ethnicity
- Socioeconomic status (SES)

For example, the prenatal life stage is the most sensitive to developmental and reproductive toxicants, and women of childbearing age should be considered as a susceptible subpopulation for any chemical with such hazards. However, women of reproductive age are not identified as a potential susceptible subpopulation in the scoping documents for pigment violet 29, TCE, NMP, PERC, or HBCD, even though EPA will consider reproductive and developmental toxicity hazards for these chemicals. This omission should be corrected during problem formulation.

III. PROBLEM FORMULATION MUST DESCRIBE EPA'S STRATEGIES FOR ASSESSING RISKS FROM AGGREGATE AND CUMULATIVE EXPOSURES

Problem formulation should also address more fully how EPA intends to address the risks resulting from cumulative and aggregate exposures to each of the 10 chemicals. The scoping documents provide minimal discussion of this essential aspect of risk evaluation design.

Section 6(b)(4)(F)(ii) requires risk evaluations to describe whether aggregate or sentinel exposures to a chemical were considered and the basis for that consideration. To properly apply either or both of these approaches in a risk evaluation, EPA must determine in advance what methodology it will employ and then incorporate it in the risk evaluation design in sufficient detail to describe the key data sources it will use to assess exposure and how they will be used. The scoping documents fail to do this. EPA should remedy this gap in problem formulation.

We believe aggregate exposure assessment will be required for all of the 10 chemicals.[8] The focus of the new law is on determining risk based on all relevant pathways and sources of exposure for the general population and vulnerable subpopulations throughout a chemical's life cycle. Thus, under section 6(b)(4)(F)(i), EPA must "integrate and assess available information on hazards and exposures for *the conditions of use* of the chemical substance" and, under section 6(b)(4)(F)(iv), must "take into account, where relevant, the likely duration, intensity, frequency and number of exposures under *the conditions of use* of the chemical substance." This emphasis on integrating risk and exposure factors across a chemical's conditions of use necessarily requires the Agency to identify all sources of exposure that may affect the general population or specific subpopulations and to determine the overall levels, frequency

[7] National Research Council. Science and Decisions: Advancing Risk Assessment. Washington, D.C.: National Academies Press; 2009.

[8] When analyzing aggregate exposures, "sentinel exposure" may be considered simultaneously, where appropriate. However, these are not mutually exclusive and EPA should not incorporate sentinel to the exclusion of aggregate.

and duration of exposures by each population or subpopulation resulting from this combination of pathways.[9]

EPA has applied the tools of "aggregate exposure assessment" successfully in several programs. For example, the 1996 Food Quality Protection Act (FQPA) directs EPA to examine aggregate exposures when issuing or renewing tolerances for pesticides in food and EPA has longstanding guidance for doing aggregate risk and exposure assessments to meet this requirement.[10]

During problem formulation, EPA should develop a roadmap for each of the 10 chemicals showing what steps it is taking to gather the necessary information for aggregate exposure assessment and how it will calculate or estimate the combined exposures resulting from multiple pathways or uses for the general population and potentially exposed or susceptible subpopulations.

Problem formulations should also address whether and how EPA will use "cumulative risk" methodologies for the first 10 risk evaluations. This, too, is an area that EPA has addressed in several guidance documents.[11] The Agency defines "cumulative risk" as "the combined risks from aggregate exposures (i.e., multiple route exposures) to multiple agents or stressors" and has explained that:

> "In cumulative risk assessments that examine risks posed by multiple chemicals, exposure assessments evaluate a population's chemical exposures through multiple routes of exposure over time. Such assessments may encompass multiple exposure timeframes in which the timing and intensity of exposures to different chemicals are examined relative to each other. It is also important to determine whether the exposures to multiple chemicals can lead to toxicokinetic interactions or toxicodynamic interactions. In addition to providing information about multiple chemical exposures in the general population, these exposure assessments identify potentially susceptible or vulnerable subpopulations in the study area and potentially unique pathways of exposure in those subpopulations."[12]

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[9] Exposures from TSCA-exempt uses such as personal care products or biocides should also be included in scoping documents and risk evaluations because of the need to account for their contribution to aggregate risk, even though regulatory authority over these products is not available under TSCA but derives from other laws administered by EPA or agencies such as FDA. This is now standard practice in implementing the Food Quality Protection Act (FQPA). The scoping documents contain limited and incomplete information on exposures to the listed chemicals from non-TSCA uses.

[10] https://www.epa.gov/sites/production/files/2015-07/documents/aggregate.pdf

[11] E.g., *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity.* U.S. Environmental Protection Agency, Office of Pesticide Programs, Washington, DC. (2002) Available at http://www.epa.gov/oppfead1/trac/science/cumulative_guidance.pdf; *Framework for Cumulative Risk Assessment,* U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Washington, DC. EPA/600/P-02/001F (2004). Available at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=54944.

[12] EPA National Center for Environmental Assessment, *Concepts, Methods and Data Sources for Cumulative Health Risk Assessment of Multiple Chemicals, Exposures and Effects: A Resource Document,* at xxviii (August 2007).

The importance of examining risks posed by multiple chemicals with overlapping pathways of exposure and common adverse health effects was also underscored by the National Academy of Sciences (NAS) in its Phthalates and Cumulative Risk report.[13]

We recommend that, in its problem formulations, EPA should commit to perform cumulative risk assessments whenever a population or subpopulation exposed to the subject chemical is also exposed to other chemicals that have similar health effects. In this situation, total risk to the relevant population or subpopulation will be a function not just of exposure to the subject chemical in isolation but of combined exposure to that chemical and other chemicals which have additive or synergistic health effects.

A compelling case for examining cumulative risks will exist where EPA is in parallel conducting risk evaluations on multiple chemicals within a class that have similar chemical structures, conditions of use and adverse health effects. An example of such a grouping is the four solvents (TCE, PERC, MC and NMP) among the initial 10 chemicals: not only is it likely that workers and consumers are exposed to all or some of these solvents simultaneously but their common hazards (i.e. neurotoxicity, reproductive toxicity) are likely to magnify the risks of such concurrent exposures. The problem formulations for these four chemicals should recognize the need to examine the cumulative risks they present and describe how EPA will evaluate cumulative risk scenarios.

IV. ONGOING USE AND DISPOSAL OF CHEMICAL PRODUCTS THAT ARE NO LONGER BEING MANUFACTURED FALL WITHIN THE TSCA DEFINITION OF "CONDITIONS OF USE" AND MUST BE ASSESSED IN RISK EVALUATIONS

Several of the 10 chemicals – asbestos, perchloroethylene (PERC), TCE, MC, carbon tetrachloride (CTC) and hexabromocyclododecane (HBCD) – contribute to ongoing exposure and risk as a result of historical manufacturing and processing activities that have been discontinued. In many cases, the current and foreseeable risks associated with these activities are significant. Nonetheless, the scoping documents provide limited information about these risk and exposure scenarios and take the position that they are outside the scope of risk evaluations except possibly as a source of information about aggregate exposure. Each scoping document contains this statement:

> "EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. For instance, the conditions of use for purposes of section 6 might reasonably include the use of a chemical substance in insulation where the manufacture, processing or distribution in commerce for that use is prospective or on-going, but would not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical

[13] National Research Council. Committee on the Health Risks of Phthalates, Board on Environmental Studies and Toxicology, Division on Earth and Life Studies. 2008. Phthalates and cumulative risk assessment: the task ahead. Washington, D.C.: National Academies Press.

substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses."[14]

We believe that EPA is incorrectly interpreting the provisions of LCSA. The definition of "conditions of use" in section 3(4) covers the "circumstances . . . under which a chemical substance is . . . known or reasonably foreseen to be . . . used or disposed of." Where a chemical is performing an ongoing *in situ* function as a result of previous manufacturing and processing activity, that function comprises a current "use" of the chemical that is "known" to be occurring.

For example, although asbestos may no longer be sold as insulation, the asbestos insulation installed in millions of US buildings continues to perform insulating functions and thus is a current ongoing "use" of asbestos. Installed asbestos-containing building materials (ACBMs) represent one of the largest sources of asbestos accessible to the general public in the US, and the largest asbestos-exposed population consists of people who occupy buildings and homes with ACBMs. Maintenance and construction activities involving ACBMs are also frequent and widespread and account for the largest present-day increase in mesothelioma illness and death in the US.[15]

Similarly, the Healthy Building Network estimates there are 66-132 million pounds (30,000-60,000 metric tons) of HBCD in insulation in existing buildings.[16] These ongoing insulation uses are and will continue to be critical sources of ongoing exposures. HBCD is also present in cars and furniture as a flame retardant and its use in these long-lived consumer articles will contribute to ongoing exposures for years to come.[17]

Equally important, the disposal of building materials or consumer products containing asbestos or HBCD is an ongoing occurrence as buildings are torn down or remodeled and cars and furniture are replaced. Thus, the resulting releases into the environment and communities comprise a "circumstance . . . under which [these chemicals] are . . . known or reasonably foreseen to be . . . disposed of." As "conditions of use" within the TSCA definition, these activities and the risks they present are likewise required to be addressed in risk evaluations under section 6(b). For both chemicals, the immediate and long-term exposures associated with disposal of *in situ* building materials and products are likely to be widespread and significant well into the future.

To exclude from risk evaluations ongoing and future exposures from *in situ* uses of discontinued products would create a sizable gap in the life-cycle assessments of risk that Congress directed EPA to conduct under the new law. This would deprive the public, scientists and regulators of a comprehensive

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[14] EPA, *Scope of the Risk Evaluation for Asbestos*, June 2017, at 8.

[15] US CDC study, "Malignant Mesothelioma Mortality – United States 1999 to 2005."

[16] Safer Chemicals, Healthy Families et al. Comments to the U.S. Environmental Protection Agency (EPA) on the Scope of its Risk Evaluation for the TSCA Work Plan Chemicals: CYCLIC ALIPHATIC BROMIDE CLUSTER or HEXABROMOCYCLODODECANE (HBCD). March 15, 2017. https://healthybuilding.net/uploads/files/saferchemicals-hbcd.pdf

[17] For chemicals like TCE and PERC, the uses that contributed to widespread contamination of groundwater and drinking water may in fact be uses for which these chemicals are still being sold, requiring EPA to include them in its risk evaluations even under its narrow interpretation of the law.

picture of one of the largest sources of continuing and future risk. One consequence would be that EPA would lack the scientific basis to ban resumption of the sale and distribution of discontinued products containing asbestos, HBCD and similar chemicals despite the unreasonable risks that they present. In addition, decision-makers would be unable to reduce ongoing exposures and impose safeguards against unsafe disposal because they would lack a meaningful risk evaluation to inform these actions. Just as TSCA provides authority to evaluate the risks associated with ongoing exposures from discontinued activities, so it gives EPA the authority under section 6(a) to reduce these risks, yet the Agency would be stymied by the absence of a risk evaluation that provides a basis for such regulation.[18]

In short, EPA must characterize and assess ongoing exposures from the use and disposal of discontinued products and determine the risks they present as part of its risk evaluations on the initial 10 chemicals. The scoping documents provide virtually no discussion of these sources of exposure to the 10 chemicals. Nothing in the law allows EPA to exclude these risks from its evaluations. EPA must correct this omission during problem formulation.

V. OZONE DEPLETION AND GLOBAL WARMING POTENTIAL POSE ENVIRONMENTAL AND HEALTH RISKS THAT FALL WITHIN THE SCOPE OF TSCA RISK EVALUATIONS

In earlier submissions, SCHF and its members highlighted data showing the high ozone depleting potential of MC, CTC and 1-Bromopropane (1-BP).[19] The scoping documents do not address these properties of the three chemicals. Nor do they examine the global warming potential (GWP) of any of the 10 chemicals. These omissions conflict with the express purpose of risk evaluations under section 6(b)(4)(A): to "determine whether a chemical substance presents an unreasonable risk of injury to health *or the environment"* (emphasis added). They also fail to meet the Agency's obligation under section 6(b)(4)(F)(i) to "integrate and assess information . . . that is relevant to specific risks of injury to health *or the environment"* (emphasis added). Ozone depletion and global warming potential clearly pose risks to the environment and they are also recognized risk factors for human health.[20,21] Nothing in the law allows EPA to exclude these risks from its evaluations.

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[18] For some chemicals like lead and asbestos, other laws administered by EPA address handling and disposal of *in situ* materials. The Agency may be able to refer the findings of its risk evaluations to the programs implementing these laws under TSCA section 9(b) in lieu of further regulation under section 6. However, there are no existing laws that address ongoing exposure from use and disposal of discontinued products containing HBCD, perfluorinated chemicals and other substances and therefore the availability of the protections afforded under section 6 of TSCA may be critical to addressing their risks.

[19] See Comments of Safer Chemicals Healthy Families on Risk Evaluation Scoping Documents for Ten Chemical Substances under the Toxic Substances Control Act, March 15, 2017.

[20] The human health risks of ozone depletion are well recognized by the Agency and documented, at least in part, on EPA's webpage, "Health and Environmental Effects of Ozone Layer Depletion:" "Ozone layer depletion increases the amount of UVB that reaches the Earth's surface. Laboratory and epidemiological studies demonstrate that UVB causes non-melanoma skin cancer and plays a major role in malignant melanoma development. In addition, UVB has been linked to the development of cataracts, a clouding of the eye's lens." https://www.epa.gov/ozone-layer-protection/health-and-environmental-effects-ozone-layer-depletion (Accessed 9-18-17)

[21] The human health risks of global warming were well recognized and documented, at least in part, by the agency prior to the arrival of Administrator Pruitt, as outlined in the legacy pages at: https://19january2017snapshot.epa.gov/climate-impacts/climate-impacts-human-health_.html While that page is being updated, "...to reflect EPA's priorities under the leadership of President Trump and Administrator Pruitt," the Agency still notes, "Climate change is having direct and indirect impacts on the health of people. More extreme

The EPA Office of Air and Radiation (OAR) has considerable expertise in both ozone depletion and global warming and has assessed some (but not all) of the 10 chemicals from the perspective of these concerns. OAR can help OCSPP draw on this prior work for its TSCA risk evaluations and perform new assessments for those chemicals whose ozone depletion and global warming impacts have not previously been examined. By addressing these impacts in TSCA risk evaluations, EPA will fulfill the law's goal of providing a comprehensive picture of environmental and health risks across the chemical's life cycle. In particular cases, it may also highlight contributors to ozone depletion and global warming that have been overlooked and may warrant restriction. Whether these impacts can be adequately addressed under the Clean Air Act (CAA) or under TSCA need not be determined in the risk evaluation itself and can be deferred to the later evaluation of risk management options under section 6(a).

VI. EPA RISK EVALUATIONS SHOULD NOT REASSESS USES OF TCE, MC AND NMP THAT WERE FULLY ASSESSED IN ITS PROPOSED SECTION 6(a) RULES

EPA has proposed to ban certain uses of TCE, MC and NMP under section 6(a) of amended TSCA.[22] As the basis for these proposed rules, EPA conducted comprehensive exposure and risk assessments on the targeted uses of the three chemicals. These assessments were subject to public comment and peer review both during their development and again as part of the rulemaking process.

In its scoping documents for the three chemicals, EPA indicates that it intends to rely on the completed assessments and will not "reassess" the targeted uses.[23] We strongly agree with this approach. It would be counterproductive for the Agency reopen these assessments for yet another round of public input and to redo the extensive analysis they contain simply so industry commenters can have another bite at the apple on findings they dislike. Moreover, we believe that the next step in the rulemakings is for EPA to issue final rules as quickly as possible. These rules, once issued, should close the book on the targeted uses and enable EPA to focus its risk evaluations on uses that have not yet been assessed. In its more comprehensive risk evaluations, however, EPA should incorporate its earlier assessments so that the exposures they describe can be accounted for in determining aggregate exposure to the three chemicals.

VII. EPA SHOULD NOT REVISIT DEFINITIVE FINDINGS IN IRIS ASSESSMENTS, WHICH REPRESENT THE AGENCY'S AUTHORITATIVE PEER-REVIEWED DETERMINATIONS OF THE HEALTH EFFECTS OF CHEMICALS

Five of the 10 chemicals – TCE, MC, CTC, PERC and 1,4-dioxane – have been assessed under the EPA Integrated Risk Information System (IRIS). The IRIS process is the Agency's authoritative mechanism for reviewing available studies, characterizing the health effects of chemicals and identifying concentrations below which these chemicals are not likely to cause adverse effects. IRIS assessments typically reflect

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weather events, heat waves, spread of infectious diseases and detrimental impacts on air and water quality are having impacts on our health." https://www.epa.gov/climate-research/human-health-and-climate-change-research (accessed 9-18-17).

[22] Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing under TSCA Section 6(a), 82 Fed. Reg. 7432 (Jan. 19, 2017); Trichloroethylene; Regulation of Certain Uses under TSCA § 6(a), 81 Fed. Reg. 91592 (Dec. 16, 2016) and Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses under TSCA Section 6(a), 82 Fed. Reg. 7464 (Jan. 19, 2017).

[23] See, e.g., EPA. *Scope of the Risk Evaluation for Trichloroethylene,* June 2017, at 33.

years of work by EPA scientists, multiple rounds of public comment, inter and intra-agency consultation, and extensive peer review, often by the Agency's independent Science Advisory Board (SAB) or the National Academy of Sciences (NAS).

Where EPA is conducting a TSCA risk evaluation of a chemical that has already been assessed under IRIS, the conclusions of the IRIS assessment should be presumed to be applicable to the TSCA evaluation as a definitive statement by the Agency of the best available science. To revisit IRIS findings would be inefficient and resource-intensive at a time when the Agency is struggling with workforce and budget reductions. It would also make the three-year statutory deadline for completing risk evaluations even more challenging by greatly expanding the scope of EPA's work effort. Most significantly, reopening IRIS findings would prolong scientific uncertainty on issues that have been addressed and resolved through an authoritative, transparent and inclusive EPA process. Like other Agency actions, IRIS assessments often give rise to differences of opinion and some stakeholders may be disappointed by the outcome. But this does not mean that EPA should reinvent the wheel and provide another bite at the apple on scientific determinations that have been made after thorough deliberation and a robust process.

In sum, the problem formulation documents on the 10 chemicals should make clear that EPA's risk evaluations will rely on previous IRIS assessments in determining health effects that those assessments address.

VIII. IN EVALUATING WORKPLACE RISKS, EPA SHOULD RECOGNIZE THE UNEVEN USE AND EFFECTIVENESS OF ENGINEERING CONTROLS, LABELING AND PERSONAL PROTECTIVE EQUIPMENT IN PREVENTING OCCUPATIONAL EXPOSURE

Several scoping documents indicate that, in its approach to occupational exposure analysis, EPA will "[c]onsider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios."[24] These measures are certainly relevant factors in analyzing occupational exposures. However, it is essential that EPA not presume that they will be effective in preventing exposure in all workplaces and for all employees. In many cases, they may in fact provide limited protection, particularly for short-term poorly trained workers in small shops and workers whose English language skills are challenged.

In its proposed section 6(a) rules for TCE, MC and NMP, EPA explained at some length why label warnings and instructions are not uniformly read, comprehended or followed and thus provide limited protection. This was not a mere opinion on EPA's part but the result of an examination of nearly fifty studies.[25] Based on this review, EPA's conclusions as described in its initial TCE rulemaking were as follows:

> "The Agency determined that warning labels and instructions alone could not mitigate the risks to the extent necessary so that TCE no longer presents the identified unreasonable risks to users. The Agency based this determination on an analysis of 48 relevant studies or meta-analyses, which found that consumers and professionals do not consistently pay attention to

[24] See, for example, US EPA (2017). Scope of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster. Pg. 45

[25] OPPT summarized these studies in a paper entitled *The Effectiveness of Labeling on Hazardous Chemicals and Other Products* (March 2016)(Ref. 33 in rulemaking docket).

labels; consumers and professional users often do not understand label information; consumers and professional users often base a decision to follow label information on previous experience and perceptions of risk; even if consumers and professional users have noticed, read, understood, and believed the information on a hazardous chemical product label, they may not be motivated to follow the label information, instructions, or warnings; and consumers and professional users have varying behavioral responses to warning labels, as shown by mixed results in studies."[26]

In the TCE vapor degreasing proposal, EPA further concluded that comprehension of warnings would be unusually challenging because of the complexity of the information conveyed:

> "EPA found that presenting information about TCE on a label would not adequately address the identified unreasonable risks because the nature of the information the user would need to read, understand, and act upon is extremely complex. It would be challenging to most users to follow or convey the complex product label instructions required to explain how to reduce exposures to the extremely low levels needed to minimize the risk from TCE. Rather than a simple message, the label would need to explain a variety of inter-related factors, including but not limited to the use of local exhaust ventilation, respirators and assigned protection factor for the user and bystanders, and time periods during pregnancy with susceptibility of the developing fetus to acute developmental effects, as well as effects to bystanders. *It is unlikely that label language changes for this use will result in widespread, consistent, and successful adoption of risk reduction measures by users and owners.*[27]

Similarly, EPA cautioned that "there are many documented limitations to successful implementation of respirators", including these well-known problems: [28]

> "Not all workers can wear respirators. Individuals with impaired lung function, due to asthma, emphysema, or chronic obstructive pulmonary disease for example, may be physically unable to wear a respirator. Determination of adequate fit and annual fit testing is required for a tight fitting full-face piece respirator to provide the required protection. Also, difficulties associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection, regardless of the assigned capabilities of the respirator. Individuals who cannot get a good face piece fit, including those individuals whose beards or sideburns interfere with the face piece seal, would be unable to wear tight fitting respirators. In addition, respirators may also present communication problems, vision problems, worker fatigue and reduced work efficiency (63 FR 1156, January 8, 1998). According to OSHA, 'improperly selected respirators may afford no protection at all (for example, use of a dust mask against airborne vapors), may be so uncomfortable as to be intolerable to the wearer, or may hinder vision, communication, hearing, or movement and thus pose a risk to the wearer's safety or health. (63 FR 1189-1190).'"

EPA based these conclusions on expert analyses by OSHA, which has extensive experience with respirators under its workplace standards.

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[26] 81 FR at 91601.
[27] 82 FR 7441 (emphasis added)
[28] 82 FR 7445

The problem formulation documents should explicitly recognize that industrial hygiene controls do not necessarily provide reliable and effective protection from exposure and that the adequacy of these controls needs to be examined on a case-by-case basis in the context of the specific establishments where the chemical is used, the makeup of the worker population in these establishments and the diligence of employers in implementing workplace controls. During problem formulation, EPA should elaborate on how these considerations will be applied for the 10 chemicals.

More generally, when considering occupational exposures, EPA needs to recognize and account for differences in levels of exposure, workplace practices and susceptibility that result in significant gradations in risk, even within a single workplace. In workplaces where chemicals and chemical products are used, exposures typically occur most intensely among a highly exposed subgroup, rather than uniformly across the population of workers. In a vehicle repair shop, for example, chemical-intensive tasks on brakes, engines, and drive-train components are performed by a subset of workers who experience high levels of exposure to aerosolized degreasing solvents, whereas other workers in the same shop who perform diagnostic or electrical work, for example, experience little or no exposure to these solvents. To effectively characterize the "conditions of use" among workers, EPA must account for the levels and duration of exposure—and therefore risk—that occurs within highly exposed subgroups as a consequence of actual workplace conditions, rather than relying on an "average" estimated exposure across a population of workers, based on an assumption of "intended" use.

IX. EPA SHOULD NOT EXCLUDE FROM THE 1,4-DIOXANE EVALUATION ITS PRODUCTION AS A BYPRODUCT OR IMPURITY, WHICH IS A SIGNIFICANT SOURCE OF CONTAMINATION OF WATER SOURCES

The scoping document for 1,4-dioxane takes the unusual approach of precluding any consideration of this substance's manufacture as a byproduct or impurity in EPA's risk evaluation:

> "In the case of 1,4-dioxane, EPA anticipates that production of 1,4-dioxane as a by-product from ethoxylation of other chemicals and presence as a contaminant in industrial, commercial and consumer products will be excluded from the scope of the risk evaluation. These 1,4-dioxane activities will be considered in the scope of the risk evaluation for ethoxylated chemicals. EPA believes its regulatory tools under TSCA section 6(a) are better suited to addressing any unreasonable risks that might arise from these activities through regulation of the activities that generate 1,4-dioxane as an impurity or cause it to be present as a contaminant than they are to addressing them through direct regulation of 1,4-dioxane"[29]

This is a deeply flawed approach that will weaken the 1,4-dioxane risk evaluation and result in inadequate risk reduction during any subsequent rulemaking under section 6(a).

1,4-dioxane is a probable carcinogen that has contaminated drinking water and groundwater in multiple parts of the country, eliciting expressions of concern from many public officials and communities. A recent analysis of data from EPA-mandated monitoring indicates that water supplies for more than 7

[29] Scope of the Risk Evaluation for 1,4-Dioxane, at 8 (June 2017)

million Americans in 27 states contain 1,4-dioxane at levels above those that EPA and other agencies believe present an acceptable cancer risk.[30]

1,4-dioxane's presence in drinking water and groundwater is linked to several pathways of release into the environment. In addition to its manufacture as a chemical product, 1,4-dioxane is a byproduct of plastic production and other chemical manufacturing processes utilizing ethoxylation. Due to its production as a byproduct, it is present as an impurity in several industrial, commercial and consumer products. 1,4-dioxane often is found in the wastewater discharged by industrial facilities and POTWs. Its presence in wastewater is likely attributable not only to intentional production and use activities but to the use and disposal of products in which it is present as an impurity.

If 1,4-dioxane's manufacture as a byproduct and presence in products and waste streams as an impurity are excluded from EPA's risk evaluation, it will have no basis for accounting for these sources of environmental release and will be unable to characterize their contribution to levels of the chemical found in drinking water, surface water and ground water. This will make its assessment of the extent and causes of water contamination incomplete and undermine its ability to conduct an informed evaluation of the options for reducing contamination and risk. Any action it later decides to take under section 6 will thus be based on inadequate information and analysis and, as a result, may be ineffective and under-protective.

Manufacture as a byproduct is plainly within the definition of "conditions of use" in section 3(4) of TSCA. There is no basis in this provision or other parts of the law for differentiating between manufacture as a byproduct and purposeful production and including one in a risk evaluation but excluding the other. And in this instance, there's no evidence (and EPA does not claim) that exposure to and release of 1,4-dioxane as a byproduct and impurity are inconsequential from a risk standpoint.[31]

While EPA suggests that it might be more efficient or effective to address byproduct production of 1,4-dioxane in a separate section 6(a) rulemaking for ethoxylated chemicals, this seems far-fetched. If EPA assesses the contribution of these chemicals to 1,4-dioxane water contamination in the current risk evaluation, it will have a sound basis to regulate their production and use under section 6(a) if they are found to present an unreasonable risk of injury.[32] Otherwise, there is no telling when EPA might mitigate water contamination resulting from byproduct production of 1,4-dioxane production. Thus far, EPA has offered no indication when, if ever, it will make a high-priority designation for ethoxylated chemicals and assess their contribution to the presence of 1,4-dioxane in the environment.

We recommend that during problem formulation, EPA add 1,4-dioxane production as a byproduct and impurity to the scope of its risk evaluation.

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[30] Environmental Working Group, HIDDEN CARCINOGEN TAINTS TAP WATER, CONSUMER PRODUCTS NATIONWIDE (September 2017).

[31] Under our interpretation of section 6(b), EPA could not exclude a condition of use from the risk evaluation scope based on low risk in any event.

[32] Section 6(a) does not limit EPA to regulating purposeful production of a chemical subject to a risk evaluation. It can regulate production by other means so long as it has been assessed in that evaluation and found to present an unreasonable risk.

X. BASED ON THE GENERAL PRINCIPLES OUTLINED ABOVE AND OTHER GAPS IN ITS SCOPING DOCUMENTS, EPA SHOULD AUGMENT THESE DOCUMENTS IN SEVERAL SPECIFIC RESPECTS DURING PROBLEM FORMULATION

Applying the general approaches outlined in these comments and in light of several omissions we identified in individual scoping documents, we recommend that EPA bolster those documents during problem formulation as follows:

1-Bromopropane (nPB)

- In our initial comments to EPA, we specifically identified nPB as being imported by companies whose primary business is supplying the cosmetics industry.[33] While the EPA has noted that authorities such as the State of California have included nPB on lists of chemicals banned in cosmetics, the potential for nPB directly or indirectly (through residues remaining from cleaning manufacturing equipment) to be present in cosmetic products is not addressed as a potential use for further assessment.
- As discussed in detail in Part V of these comments, EPA failed to address the ozone depletion potential of nPB.
- While the scoping document includes references to those exposed to nPB from use of the chemical in consumer products, as well as those co-located with dry cleaning facilities utilizing the chemical, it does not clearly identify people who may be further exposed from chemical residuals, such as those wearing clothing cleaned with nPB or their children. This pathway is not discussed, even though the scoping document for PERC includes it from the similar use of PERC in dry cleaning.

Asbestos

- EPA's scoping document claims that public comments were not received on various imported asbestos containing products available in the United States: "Products available from several online retailers and distributers include brake blocks, aftermarket friction products, roof and non-roof coatings, and gaskets, most of which are imported. No public comments were received regarding these uses." However, we submitted detailed comments highlighting all of these items and more, including other building products. [34]
- EPA's failure to include a lengthy list of legacy uses, as further discussed in Part IV of these comments, is especially problematic for asbestos which was extensively sold and distributed and remains widely present and in use in our buildings and cities.
- The recycling of legacy materials, notably asphalt shingles containing asbestos, is a unique and ongoing use of the substance, and in particular is worthy of additional consideration by the EPA, as discussed in our initial comments.[35]

[33] EPA-HQ-OPPT-2016-0741-0027 at PDF Pages 25, 27, 31.
[34] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 19, 25-27
[35] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 21-22

- There is evidence that asbestos has been present in significant levels in some talc products as the result of colocation of asbestos and talc deposits, as we discussed in our initial comments.[36] This use and ongoing exposure are not addressed in the scoping document.

- The scoping document fails to look at the risks of exposure to those who are upstream to the process of utilizing asbestos in chlor-alkali processing. This would include miners and packaging workers (who, while likely abroad, are still being exposed as a result of the substance's uses in the US considered by the EPA), as well as transportation workers, first responders, and community members who may be exposed in the shipment and transfer of asbestos to the chlor-alkali facilities.

- The absence in the scoping document of total import volumes for asbestos is troubling because it deprives the public of an understanding of the aggregate quantities of asbestos present in the US. In fact, the Asbestos Disease Awareness Organization, along with the Environmental Working Group, released a statement on September 19 that, based on data from the Department of Commerce and US International Trade Commission, 705 metric tons of raw asbestos were imported in 2016, compared to 343 metric tons in 2015. This significant increase in imports is important information that should be given prominence in the problem formulation document for asbestos.

Carbon Tetrachloride (CTC)

- As discussed in detail in Part V of these comments, EPA failed to address the ozone depletion potential and global warming potential of CTC in its scoping document. This is particularly problematic for CTC, as its use as a feedstock or intermediary was exempted from the Montreal Protocol on the false assumption that CTC production would be phased out. In actuality, CTC production is poised for an increase due to its use in HFO manufacture, as we discussed on our initial comments.[37]

- As discussed in detail in Part III of these comments, EPA failed to describe with any specificity how it will look at aggregate and cumulative exposures. In the CTC scoping document, EPA seems to specifically discredit the need for this consideration. The Agency highlights the fact that some individuals may be exposed to CTC through vapor intrusion of ground sources of CTC into their home, but then states that, ". . . this route is not likely to be significant given the agency's identified conditions of use . . ." Clearly, whether the CTC inhaled by a resident is from the vapor intrusion or from an adhesive product, they face potential health risks from it. The Agency must consider all uses and sources of exposure in the risk evaluation in order to accurately assess the human health risk and fulfill its statutory obligations.

Cyclic Aliphatic Bromides Cluster (HBCD)

- As detailed in Part IV of these comments, EPA must not exclude the ongoing use and disposal from past introduction of HBCD in a variety of products. Significant exposures will continue to occur as products incorporating HBCD move through their lifecycle, and these exposures must be considered in the risk evaluation.

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[36] EPA-HQ-OPPT-2016-0736-0064 at PDF Pages 18-19

[37] EPA-HQ-OPPT-2016-0733-0023 at PDF pages 4-5, 19

N-Methylpyrrolidone (NMP)

- As we documented in our initial comments to the EPA, NMP has been used in the manufacturing of coating for the insides of aluminum spray cans.[38] Even products not including deliberate addition of NMP may therefore be contaminated with NMP, and this exposure pathway should be considered by the Agency.

- As detailed in Part II of these comments, EPA failed to provide specifics on susceptible subpopulations. While the Agency acknowledges that reproductive effects are to be assessed, considering the well-documented reproductive toxicity of NMP, the Agency needs to better detail how the risks to women of childbearing age will be addressed.

Methylene Chloride (MC)

- While the scoping document includes a use categorization for "other consumer products" including novelty "Drinking Bird" items, we identified an additional item,[39] a "Novelty Christmas Bubbling Night Light" labeled as containing MC but not previously included in EPA's "Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Methylene Chloride." These consumer-oriented uses that are attractive to children illustrate the need to be comprehensive in the determination of "reasonably foreseeable" uses.

XI. EPA MAY NOT PREJUDGE THE ABSENCE OF ADVERSE EFFECTS FOR PARTICULAR END-POINTS AT THE SCOPING STAGE AND SHOULD DEFER SUCH CONCLUSIONS UNTIL THE SYSTEMATIC REVIEW STAGE OF ITS RISK EVALUATION

In some scoping documents, EPA has decided that the subject chemical does not raise concerns for particular endpoints and, therefore, it will not address these end-points in its risk evaluation. Examples are given in the table below where EPA concludes that HBCD, NMP and pigment violet 29 are not genotoxic:

Chemical	Example Text from EPA Scoping Document
HBCD	"Available data suggest that HBCD is not genotoxic. Existing assessments have also concluded, based on genotoxicity information and a limited lifetime study, that HBCD is not carcinogenic (NICNAS, 2012; EINECS, 2008; TemaNord, 2008; OECD, 2007). Unless new information indicates otherwise, EPA does not expect to conduct additional in-depth analysis of genotoxicity or cancer hazards in the risk evaluation of HBCD at this time."[40]
NMP	"NMP is not mutagenic, based on results from bacterial and mammalian *in vitro* tests and *in vivo* systems and is not considered to be carcinogenic (RIVM, 2013; OECD, 2007; WHO, 2001). Unless new information indicates otherwise, EPA does not expect to conduct additional in-depth analysis of genotoxicity and cancer hazards in the NMP risk evaluation."[41]

[38] EPA-HQ-OPPT-2016-0743-0031 at PDF page 18
[39] https://www.amazon.com/Bubble-Nightlight-Novelty-Christmas-Bubbling/dp/B00PV61HXC/
[40] EPA, *Scope of the Risk Evaluation for Cyclic Aliphatic Bromides Cluster, June 2017, at.* 36
[41] EPA, *Scope of the Risk Evaluation for N-Methylpyrrolidone,* June 2017, *at* 36

Pigment violet 29	"Testing for carcinogenicity of Pigment Violet 29 has not been conducted. However, negative genotoxicity results, structure-activity considerations and the expectation of negligible absorption and uptake of Pigment Violet 29 (based on very low solubility), indicate carcinogenicity of Pigment Violet 29 is unlikely. Unless new information indicates otherwise, EPA does not expect to conduct additional, in-depth analyses of genotoxicity and cancer hazards in the risk evaluation of Pigment Violet 29."[42]

EPA cannot reach such definitive conclusions at the scoping stage. The required course under the law is to proceed with a systematic review of the relevant data (a process that EPA strongly endorses) and withhold any conclusions about particular end-points until this review is complete.

In the case of HBCD, for example, a more thorough review would reveal two recent studies indicating carcinogenic potential. One suggests that HBCD could "enhance progression of prostate cancer by modulating growth and migration of LNCaP prostate cells,"[43] and the other concludes the genotoxicity of HBCD is dose-dependent and related to DNA repair.[44] These new studies are examples of the need for EPA to assure that it has fully considered all the available data through the systematic review process in order to avoid premature and possibly incorrect decisions to drop particular end-points at the scoping stage.

XII. PROBLEM FORMULATIONS SHOULD HIGHLIGHT ASPECTS OF USE AND EXPOSURE WHERE AVAILABLE INFORMATION IS INSUFFICIENT AND REQUEST OR REQUIRE SUBMISSION OF THIS INFORMATION BY INDUSTRY

Our own research on the 10 chemicals and the scoping documents themselves confirm that there are significant gaps in the use and exposure information available to EPA and that they will weaken the quality of EPA's risk evaluations unless filled. Although the timeframe for completing risk evaluations is compressed, there is still a window for augmenting the information-base used to conduct them. To take advantage of this opportunity, EPA should include in each problem formulation document a description of information on use and exposure that is lacking and a request that industry and other interested parties submit or obtain that information as expeditiously as possible.

EPA should also signal its readiness to use its mandatory information collection authorities under TSCA to fill data-gaps where voluntary submissions are not timely or adequate. The LCSA expands these authorities and streamlines the process for exercising them, removing the barriers to information development that hamstrung EPA under the old law. For example, section 4 now authorizes EPA to issue orders where necessary to "perform a risk evaluation." Such orders can be used to require industry to develop new information on the frequency, levels and duration of exposure for a chemical's conditions of use. Alternatively, EPA can use its subpoena authority under section 11 to obtain such information that already exists but has not been provided to EPA. EPA should specify in the problem formulation document its roadmap and timetable for filling data gaps using these authorities.

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[42] EPA, *Scope of the Risk Evaluation for Pigment Violet 29*, June 2017, at 29.

[43] Seung-Hee Kim, et al, 2016. Influence of hexabromocyclododecane and 4-nonylphenol on the regulation of cell growth, apoptosis and migration in prostatic cancer cells. Toxicology in Vitro. 32:240-247. April 2016.

[44] Rui Jing Li, et al. Hexabromocyclododecane-induced Genotoxicity in Cultured Human Breast Cells through DNA Damage. Letter to Editor. Biomedical and Environmental Sciences. 30(4): 296-300.

Where the database available for a risk evaluation is incomplete, it is critically important that EPA not equate the absence of data with the absence of risk. For example, if EPA lacks data to assess a chemical's carcinogenicity, its risk evaluation needs to clearly state that cancer risk has not been addressed, that the chemical may or may not present such a risk, and that this end-point is outside the scope of its evaluation because of the absence of data. EPA should make the same disclaimers for conditions of use that cannot be adequately characterized, even by using default assumptions or extrapolation methods, because basic information about the nature of the use and scope and extent of exposure is unavailable.

XIII. EPA NEEDS TO LIMIT REDACTION FROM SCOPING AND PROBLEM FORMULATION DOCUMENTS OF CRITICAL INFORMATION CLAIMED CBI SO THAT TRANSPARENCY AND PUBLIC PARTICIPATION IN THE RISK EVALUATION PROCESS ARE NOT IMPAIRED

The scoping documents omit critical exposure and use information that has been claimed as confidential business information (CBI) that must be withheld from disclosure under TSCA. In some cases, the information is as basic as the total volume of the chemical manufactured and imported in the US. For example, the scoping documents fail to provide total manufacture/import volumes for asbestos, HBCD and pigment violet 29. Not only is this information obtainable in the public domain but it is fundamental to public understanding of the risks posed by these chemicals and, therefore, to informed public participation in the risk evaluation process.[45]

During problem formulation, EPA should make a concerted effort to limit the redaction of CBI-claimed production, use and exposure data that are essential for the transparency of the risk evaluation process. Several tools can be used for this purpose.

First, section 14(b)(3) of TSCA declares that "information not protected from disclosure" includes:

> "any general information describing the manufacturing volumes, expressed as specific aggregated volumes or . . . expressed in ranges."
>
> "a general description of a process used in the manufacture or processing and industrial, commercial or consumer functions and uses of a chemical, substance, mixture or article containing a chemical substance or mixture . . ."

This provision compels the disclosure of much of the information in scoping documents claimed CBI.

Alternatively, section 14(d)(7) provides that the Administrator may disclose information otherwise warranting CBI protection if he or she "determines that disclosure is relevant in a proceeding under this Act." The risk evaluations that EPA is conducting on the 10 chemicals under section 6(b)(2)(A) of TSCA represent a "proceeding" under TSCA. Information submitted by industry on the 10 chemicals is plainly "relevant" to these evaluations because it will inform how EPA assesses exposures and related risks

[45] For asbestos, SCHF and Environmental Health Strategy Center were able to use US government data accessible through the Panjiva database to determine annual asbestos imports over an extended period. As noted above, a more recent analysis of import data by the Asbestos Disease Awareness Organization shows that asbestos imports doubled in 2016, a startling finding that should be central to EPA's risk evaluation because of its implications for exposure to asbestos in the US.

associated with manufacture, processing and downstream commercial and consumer use. Thus, EPA can and should decide to disclose all information on the 10 chemicals notwithstanding any CBI claims.

Finally, to the extent these grounds for disclosure do not apply, EPA should use its authority under section 14(f)(1)(C) to require immediate substantiation of CBI claims for information for which "disclosure would be important to assist the Administrator in conducting risk evaluations . . . under section 6." This provision should be applied broadly to accomplish disclosure of all information that would be of value to the public in commenting on risk evaluations.

CONCLUSION

Our groups appreciate the opportunity to comment on the 10 scoping documents and look forward to continued dialogue with the Agency as it develops problem formulation documents and proceeds with risk evaluations on the 10 chemicals.

If you have any questions, please contact SCHF counsel, Bob Sussman, at bobsussman1@comcast.net or 202-716-0118.

Respectfully submitted,

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Laurie Valeriano, Executive Director, Toxic-Free Future

Linda Reinstein, President, Asbestos Disease Awareness Organization

September 19, 2017

Region 1

Hot Topics:

Parties Reach Significant Agreement in Principle on Priority Superfund Site
EPA, the State of Rhode Island, and Black & Decker have reached a mediated agreement in principle on the Consent Decree (CD) and Statement of Work (SOW) at the Centredale Manor Site in North Providence, RI. EPA will likely sign in early June. The CD will be lodged with the Court in mid-June. Under the terms of the CD, the PRPs will begin performance on the RD upon lodging. This Site is on Administrator Pruitt's list of sites targeted for immediate, intense action.

NH MS4 Permit Mediation Kicks-off
This week, mediation began among the appellants of the NH MS4 general permit for small municipalities. While the state of New Hampshire is not a party to the litigation, Region 1 secured the agreement of all parties to the state's participation in the mediation. Mediation for the Massachusetts MS4 general permit, which started last week, continues.

Lead Paint Removal Contractors Receive Notice of Upcoming Lead Inspections
Region 1 began outreach to contractors located in our two focus communities of Portsmouth, NH and Portland, ME. An initial mass mailing of 171 letters, including 23 to those whose lead removal firm certification has expired were sent to Portsmouth contractors. The letters provided information on EPA's initiative, lead-based paint rules, lead in drinking water, and on how to identify EPA accredited trainers in their area. A similar mass mailing to Portland contractors is expected to go out next week. Region 1 is coordinating these efforts with local and state officials as well as community groups.

Upcoming Major Decisions and Events:

Charles River (Massachusetts) Receives an A- in Annual Water Quality Report Card Announcement
On June 1, Region 1 will announce its 23rd annual grade for water quality in the Charles River. The grade of A- reflects 2017 data showing that the river met boating standards 95% of the time and swimming standards 72% of the time. This is only the second time that the Charles has achieved a grade this high.

RA Dunn, Erin Chancellor and Steven Cook to meet with concerned citizens at Coakley Superfund Site
On June 4, RA Dunn, Adviser Erin Chancellor and Deputy AA Steven Cook will visit the site and meet with Community Activist Jillian Lane and concerned neighborhood citizens. This visit is a follow-up to Albert Kelly's commitment to Jillian Lane that he would visit the site.

RA Dunn and Erin Chancellor to participate in two New Bedford Harbor events with Mayor Mitchell
On June 5, RA Dunn and Adviser Erin Chancellor will participate in an onsite celebration of the completion of the Pierce Mill Cove cleanup and the reopening of Riverside Park. Following the celebration, they will participate in a roundtable with Mayor Mitchell on his plans for economic growth and development of the New Bedford Harbor. MassDEP and USACE will also be in attendance.

Region 2

Hot Topics:

Consent Order with National Grid at Gowanus Canal Superfund Site
On 5/24 Region 2 finalized this consent order, which provides for extensive cleanup work with an estimated value of about $100 million. Under the order National Grid will construct a sealed barrier wall to contain coal tar migration from its former Fulton Manufactured Gas Plant site; remove coal tar at two properties following their acquisition by New York City for construction by the City of an 8-million gallon CSO retention tank (required under the 2013 Record of Decision for the site); remove coal tar from beneath an adjacent City-owned public park and swimming pool; and develop plans for and provide a temporary and permanent replacement swimming pool facility. The order provides for close coordination of work by National Grid with work required by EPA's 2016 consent order with New York City addressing the property acquisition, design of the CSO retention tank, and related matters. Finally, the Order provides for the reimbursement of EPA's oversight costs.

"General Duty Clause" Compliance Order Issued to Shamrock Enterprises
On 5/29 Region 2 issued an order regarding Shamrock's failure to comply with §112(r) of the Clean Air Act, known as the "general duty clause," at its Franklinville, NJ facility. At the facility, which is near residences, Shamrock sells, stores, and handles compressed gases including acetylene and propane, which are extremely hazardous substances. Shamrock failed to identify potential hazards from accidental releases, and to design and maintain a safe facility so as to prevent releases. EPA inspected the facility at the request of New Jersey; state and local agencies participated in the inspection. The Order calls for proper handling and storage of extremely hazardous substances, and compliance with applicable industry standards and safety regulations, including fire code requirements.

Chemours Chambers Works/Deepwater, NJ
Chemours responded to EPA's questions regarding GenX, and we have begun our review of the document. Within the next one to two weeks we expect to start receiving results of Chemours' sampling for GenX in nearby monitoring and residential wells starting as early as next week. NJDEP has received an Order to Show Cause initiated by the Township of Carney's Point, which is near the Deepwater facility. The Town seeks NJDEP approval of a public participation plan for the Township. Chemours has agreed to develop a public website similar to the one that was set-up for Chemours' Fayetteville, NC site; development of the website should take about a month.

Wolff-Alport Superfund Site, Brooklyn, NY
RA Pete Lopez and staff met on 5/30 with Congresswoman Nydia Velasquez to brief her on progress at this site. At her request, Region 2 will organize a public availability session to update the community about the work at the site, probably on June 18.

Upcoming Major Decisions and Events:

Confidential: Settlement with NYC Housing Authority (NYCHA)
As of this writing, the announcement of the settlement with NYCHA is expected to occur on June 5th at noon at the U.S. Attorney's Office in Manhattan. We expect that Susan Bodine will attend.

June 6: RA Pete Lopez will give keynote remarks at Columbia Law School's "Key Environmental Issues in EPA Region 2," a biennial conference co-sponsored by the American Bar Association. The conference will also feature a panel discussion among the RA and the environmental commissioners of NY, NJ, PR and the USVI.

June 7: Deputy Administrator Wheeler will be visiting Region 2, with a planned tour of Gowanus Canal.

June 18: Region 2 leadership will be participating in a Lake Guardian event in Rochester, NY to highlight the survey of Lake Ontario (dive and sampling missions by EPA staff).

Region 3

Hot Topics:

Lead-Based Paint Program Continues Outreach Efforts in Philadelphia
LCD managers and staff met with the City of Philadelphia Department of Public Health's Director of Environmental Health Services and the Program Administrator of the Lead and Healthy Homes Program to continue discussing potential partnership opportunities. The City expressed interest in working together on outreach campaigns, especially to child care centers in Philadelphia. LCD learned more about the City's laws and programs related to lead-based paint in child care centers, as well as communication channels, outreach initiatives, training sessions, and inter-agency meetings, which may provide opportunities for collaboration. LCD will speak with the City again in June to follow up on this conversation.

Administrative Settlement Executed on [HYPERLINK "https://cumulis.epa.gov/supercpad/cursites/csitinfo.cfm?id=0300034"], **New Castle, Delaware**
An Administrative Settlement Agreement and Order on Consent (AOC) for remedial design (RD) was executed on May 22, 2018, which is 31 work days after EPA waived special notice procedures and invited the Delaware Sand & Gravel Landfill (DS&G) Remedial Trust to negotiate the agreement. Respondents to the AOC will complete pre-design investigations and the RD and install two groundwater interceptor wells to begin implementation of EPA's December 2017 Amendment No. 2 to the 1988 Record of Decision. EPA also issued letters to the potentially responsible parties at the adjacent Army Creek Landfill Superfund site to encourage their continued negotiation of an allocation agreement with the DS&G Remedial Trust for performance of the remedial action under a future consent decree.

EPA Region III Reissues DC MS4 Permit
On Wednesday, May 23, 2018, EPA reissued the Municipal Separate Storm Sewer System NPDES permit for the District of Columbia (DC MS4).
The DC MS4 permit had been administratively extended since it expired in October 2016. EPA worked closely with the District of Columbia in drafting this permit and considered numerous public comments from a variety of stakeholders. The DC MS4 permit will take effect June 22, 2018.

EPA Certified Lead Renovator Company Pleads Guilty for Failing to Follow Safe Work Practices to Reduce a Lead Hazard Exposure Under Toxic Substances Control Act (Criminal Case No. 1:18-Cr-00157 Middle District of Pennsylvania)
On May 22, 2018, Bitner Brothers Construction Company, Inc. (Bitner Brothers) of Carlisle, Pennsylvania entered a two-count plea for violating safe work practices promulgated under the Toxic Substances Control Act (TSCA), and aiding and abetting. In February 2017, Bitner Brothers conducted the work inside two apartments In Harrisburg, Pennsylvania while families with small children were present. The company failed to comply with the regulation requiring that power grinding must have a shroud or containment system equipped with a HEPA vacuum during the renovation pursuant to Title 15, United States Code, Sections 2689 and 2615(b).

As part of the plea agreement, the defendant, and its President and owner, Charles H. Bitner, Jr., were directed not to undertake new work contracts that require a special skill, training or certification related to the handling and/or management of lead, including lead-based paints, for the period of probation. Magistrate Judge Martin Carlson accepted the plea and set a sentencing date for September 18, 2018. The maximum penalty for that offense is a fine of $200,000, a maximum period of probation of five years, as well as the costs of prosecution or probation, and a special court assessment.

Upcoming Major Decisions and Events:

None.

Region 4

Hot Topics:

Daicel Safety Systems (Beaver Dam, KY)
Key Message: During the week of May 29, 2018, Region 4 Administrator Trey Glenn informed the Commissioner for the Kentucky Department for Environmental Protection that EPA will defer to the state regarding the permit for Daicel Safety Systems.

Subtropical Storm Alberto
Key Message: Region 4, in coordination with Florida, Alabama, and Mississippi, conducted an assessment to identify any impacts from the storm to wastewater treatment facilities, Risk Management Plan facilities, or Superfund sites. No issues were identified.

Kentucky 2016 303(d) List Approval
Key Message: Region 4 has determined that Kentucky's 2016 303(d) List update substantially meets the intent of section 303(d) of the CWA and the EPA's implementing regulations. The Region is approving all the changes identified by the Commonwealth of Kentucky. Specifically, Region 4 approves Kentucky's decision to include approximately 350 additional pollutant-waterbody combinations on the section 303(d) list, and concurs with the delisting of 68 pollutant-waterbody combinations, Region 4 does not anticipate objections from stakeholders or the public nor anticipates media interest.

Upcoming Major Decisions and Events:

Decisions
Grenada – The Region's position based on the information and proposed remedy submitted by the PRP.

Events
Regions 4, 6 and Gulf of Mexico Program Office Meeting
On June 4, 2018, Region 4 Administrator Trey Glenn, Region 6 Administrator Anne Idsal, and other regional senior leadership will meet to discuss future engagement and support from the Gulf of Mexico Program Office and tour ongoing projects with partner agencies. New Orleans, LA. Closed Press.

Hurricane Preparedness Meeting
On June 5, 2018, Region 4 Administrator Trey Glenn will participate in a hurricane preparedness meeting with other senior leaders from Region 4, Region 6, and various headquarters offices. New Orleans, LA. Closed Press.

Region 5

Hot Topics:

EPA Reaches Agreement in Principle with Crown Enterprises Inc. Regarding the McLouth Steel Property
Key Message: Crown Enterprises and its affiliate, MSC Land Company LLC, are expected to acquire the property, which is currently held by the Wayne County Land Bank.

The agreement will provide the companies with legal protections in exchange for cleanup work at the property. EPA, Michigan Department of Environmental Quality, U.S. Department of Justice, Crown and MSC devoted considerable time to this agreement, and EPA believes it will benefit the public by allowing for the reuse of contaminated land. EPA expects that the agreement can be finalized within the next 120 days.

EPA Responds to Office of Inspector General's Flint Report
Key Message: On May 30, 2018, Region 5, in coordination with OECA and OW, issued a formal response to the OIG's Flint report, including concurrence with all nine of the OIG's recommendations. The response also included corrections to a series of identified factual inaccuracies that were contained in the OIG's report.

The agency is working expeditiously to implement the recommendations made by the OIG.

EPA and MDEQ Coordinating on Draft Back Forty Mine Permit
Key Message: Once MDEQ shares a revised draft, the Region will send a letter to MDEQ indicating that the current draft satisfies EPA's objections if issued by June 6.

The Region agrees that the proposed conditions would satisfy EPA objections to the State's draft CWA 404 permit, and has provided suggestions to clarify the permit language. MDEQ will revise the draft to include clarifying language and will share with EPA this week.

Upcoming Major Decisions and Events:

Region 5 to Brief Administrator Pruitt on USS Lead on June 6, 2018
Key Message: The Region will be briefing Administrator Pruitt on the draft USS Lead Zone 1 Proposed Plan Record of Decision Amendment.

The USS Lead site is on the Administrator's Emphasis List and the completion of the Zone 1 Record of Decision Amendment is the completion milestone referenced for this site. Given the sensitivity of the issues within the community and the potential for the Amendment to be greater than $50 million, a briefing for the Administrator is required and is being coordinated with HQ.

EPA to Hold a Series of Public Engagement Meetings for the Great Lakes Restoration Initiative Action Plan III
Key Message: Meetings will be held in Toledo, Ohio; Rochester, N.Y.; Duluth, Minn.; Milwaukee, Wis.; Saginaw, Mich.; and Chicago, Ill., between June 13 and August 7, 2018.

EPA and its federal partners are in the process of developing GLRI Action Plan III, which outlines Great Lakes restoration focus areas and goals for the years 2020-2024. The proposed plan will be available for formal public comment this fall.

Region 6

Hot Topics:

HP Cylinders Emergency Response, Baytown, Texas
The company was called Stillwater Consultants, LLC, and it abandoned over 500 cylinders of compressed gas. EPA expects the contractor bids to begin to come in this week. Texas Commission on Environmental Quality (TCEQ) continues to provide 24-hour site security and conduct daily fence line air monitoring. All fence line readings have been non-detect to date. The site remains secured and conditions are stable, but being monitored closely. EPA's Emergency Response contractors are on standby in Houston and ready to respond in the event the situation changes.

US/Mexico Border Wall, McAllen, Texas
Under the recent appropriations bill the Secretary of Homeland Security is required to consult with the Secretary of Interior and the Administrator of the U.S. Environmental Protection Agency as they plan to replace existing and build the new wall and fence along the border. While the Secretary of Homeland Security issued waivers on many border wall/fence projects in 2017, DHS would like to address environmental health concerns upfront in the design and planning phase where possible. EPA joined federal officials to tour the Border Wall along the Lower Rio Grande near McAllen, Texas this week.

Carbon Black CAA Judicial Settlements, Oklahoma, Louisiana, Texas
On May 25, 2018, DOJ and EPA filed a motion to enter judicial settlements for the following consent decrees (CDs), all part of EPA's National Carbon Black Initiative: Cabot Corporation (2nd amendment to existing CD), Orion (CD), Columbian Chemicals (CD), and Sid Richardson (CD). In addition, Continental Carbon (amendment to existing CD), a motion to enter was filed and granted.

Sandow Power Plant, Rockdale, Texas
EPA anticipates that as early as June 4, 2018, the U.S. Department of Justice (DOJ) may notify Sandow Power Company LLC (SPC), an affiliate of Luminant Generation Company LLC, that the United States will join in a motion to the Court to terminate the Consent Decree (CD) relating to SPC's coal-fired power plant in Rockdale, Milam County, Texas. On January 11, 2018, SPC permanently retired Sandow Units 4 and 5, the subjects of the CD. On February 7, 2018, SPC sent a letter to DOJ and EPA requesting that the United States join in a motion to the Court to terminate the CD.

Anchor Glass Container Corporation, Henryetta, Oklahoma
The Department of Justice (DOJ) and EPA are expected to sign a Consent Decree (CD) with Anchor Glass Container Corporation (Anchor). The settlement includes glass facilities in Regions 2, 4, 5, and 6; two states, Indiana and Oklahoma, also participated in the negotiations and plan to sign the CD. The Anchor facility in Region 6 is located in Henryetta, Oklahoma, and the settlement resolves Clean Air Act violations for commencing construction without obtaining permits to comply with the Act's Prevention of Significant Deterioration requirements. Anchor will install air pollution control equipment and pay a $1.1-million-dollar penalty, with $650,000 going to the United States, and $325,000 going to each of Indiana and Oklahoma.

New Mexico NESHAP/NSPS Delegation
EPA withdrew its direct final approval of the updated of NESHAP and NSPS provisions to New Mexico Environment Department. EPA received adverse comments regarding NMED's ability and available resources to implement and enforce the NESHAP and NSPS standards.

Upcoming Major Decisions and Events:

St. James Parish South Louisiana Methanol LP, Louisiana

Region 6 intends to issue a federal register notice announcing the Administrator's decision on the South Louisiana Methanol Title V Petition. The date, while intended for June 15, is subject to change based on internal deliberations on the merits of the petition.

Arkansas State Implementation Plan
Region 6 intends to take final SIP action by June 20 to raise ADEQ's minor NSR permitting and de minimis thresholds. EPA received significant public comments on the proposed SIP changes from Sierra Club and more specifically on our 110(l) analysis (anti-backsliding into nonattainment) for the action. EPA has developed a response to those comments in the final action. This will address two backlog SIP actions.

June 4	RESTORE Project Tour, New Orleans, Louisiana
June 5	Hurricane Preparedness Meeting, New Orleans, Louisiana

Region 7

Hot Topics:

Sporlan Valve Site Meeting Hosted by Missouri Department of Natural Resources (MDNR)
Key Message: Region 7 attended a state organized stakeholder meeting on the potential NPL listing of the Sporlan Valve site in advance of a public availability session next week.

- On May 30, MDNR and EPA Region 7 met with Washington, MO City officials, Franklin County Commissioners, the Franklin County Health Department, and State Representatives to discuss local support for adding the Sporlan Valve site to the Superfund National Priorities List (NPL). TCE has been detected in groundwater, soil gas, and indoor air of residential homes adjacent to the site and a series of actions have been taken by EPA to mitigate the threat of vapor intrusion including sampling for TCE vapors in homes and installing vapor mitigation systems. To date, EPA has installed and/or overseen the installation of 19 vapor mitigation systems at homes adjacent to the site.
- On June 5, EPA will host a Public Availability session in Washington, MO to discuss the proposal of the site to the NPL. MDNR and the Governor of Missouri want local support for proposed listing prior to EPA moving forward.

Upcoming Major Decisions and Events:

Hurricane Preparedness Meeting
Key Message: On June 5, Regional Administrator Jim Gulliford will travel to New Orleans, LA to attend the Hurricane Preparedness Meeting.

- The purpose of the meeting is to consider and address lessons learned during prior natural disasters, most notably from the 2018 hurricane and wildfire seasons, to improve EPA's natural disaster preparedness, response, and recovery efforts.
- Several EPA regions and offices have been invited to participate.

OECA Assistant Administrator Visit
Key Message: On June 6, OECA Assistant Administrator Susan Bodine will visit Region 7. Agenda sessions include opportunities for AA Bodine to meet with Superfund and Criminal Investigation Division staff, participate in an All Hands meeting for Region 7 staff, and discuss enforcement direction.

Assistant Deputy Administrator and Chief of Operations Visit
Key Message: On June 7, Assistant Deputy Administrator and Chief of Operations Henry Darwin will be at Region 7 to assess progress and provide coaching on visual management tools created during Region 7's ELMS training in late April.

Region 8

Hot Topics:

Notice of Intent to Delete the Davenport and Flagstaff Superfund Site published in FR
On June 4, EPA and the Utah Department of Environmental Quality will invite the public to comment on the proposal to delete the remaining portions (OU2, OU3 and the remaining portions of OU1) of the Davenport and Flagstaff Smelters Superfund Site from the National Priorities List.

Upcoming Major Decisions and Events:

Site Visit to Basin Electric Laramie River Station
On June 6th, R8 staff will join the Wyoming Department of Environmental Quality at the Basin Electric Laramie River Station to learn more about NO_x emission controls being installed in accordance with a settlement agreement entered into by the EPA, the state of Wyoming and Basin Electric. In accordance with the settlement agreement, the EPA must propose by October 5, 2018, a revised Federal Implementation Plan for the Laramie River Station reflecting, among other things, the agreed upon NO_x controls.

Region 9

Hot Topics:

Hawaii Volcano Response
RA Mike Stoker met with Hawaii Governor Ige and key State leaders. We shall brief Dep. Administrator Wheeler Friday regarding our air monitoring and public communication. We plan to launch a publicly accessible website with real-time air-monitoring data (SO2, H2S, and particulates) from our 12 stations. With FEMA and HHS, we'll increase risk communication and community engagement where the County has been reticent. The State is requesting of FEMA increased federal support under ESF 8 and ESF 10 (e.g. 10 additional air monitoring stations). We're in close contact with the National Guard and Civil Support Team to address electrical power, cell phone coverage, and access to our air monitoring network.

National Oil Enforcement
We're hosting an EPA-only national oil enforcement meeting in the Regional Office, with participation from the Regions, OLEM and OECA.

Upcoming Major Decisions and Events:

Nevada
On June 5-6, RA Mike Stoker will host the Nevada Dept. of Environmental Quality executive team for two days of program meetings in San Francisco.

Arizona
June 6-7, RA Mike Stoker with participate in the Sen. McCain-hosted Rio Salado tour and meetings with Federal and State agencies, to focus on improving the environmental and economic vitality of the Salt River riparian corridor. On June 7, he'll meet with Arizona DEQ Director Misael Cabrera and present the newly awarded Performance Partnership Grant.

So. California
June 8-9, RA Mike Stoker will meet with the EPA San Diego Border Office staff and be briefed on our Mexican Border program. He will address the California Independent Petroleum Association annual conference.

American College of Environmental Lawyers
Alexis Strauss will speak June 1 at the San Francisco regional meeting of this group, which convenes in each Region and has in recent months hosted speaking engagements with Ken Wagner and Cathy Stepp.

Region 10

Hot Topics:

Region 10 Assists Salem, OR With Harmful Algal Bloom Event and Do-Not-Drink Advisory
A harmful algal bloom has produced high concentrations of microcystins in Detroit Lake, which serves as the primary drinking water source for the City of Salem, Oregon. A recreational water advisory was issued for the lake on May 23rd, when concentrations of microcystins were measured at more than 10 times the Oregon Health Authority advisory level. Out of an abundance of caution on May 29, the City issued a do-not-drink advisory for individuals with compromised immune systems and small children. An advisory update will be issued after additional sample results come in on May 31st. EPA's role is to provide technical assistance to the state and City of Salem and answer questions related to HABs effects and treatment options. Over the past several years, Region 10 has worked to build capacity among states, tribes and local governments to identify HABs problems, the role of nutrients, and response actions, including hosting workshops and webinar-based meetings. Region 10 is following the draft HABs Response Plan template to manage our coordinated response to this incident with HQ, state, and local officials.

Upcoming Major Decisions and Events:

Region 10 Approves Idaho's NPDES Program
On June 5th, Region 10 and EPA headquarters will participate in a signing ceremony in Boise, Idaho announcing EPA's approval of the Idaho Department of Environmental Quality's wastewater discharge permit program (IPDES). Starting July 1, 2018, IDEQ will begin issuing and enforcing water pollution permits for industry and municipalities across the state. IDEQ has been working for several years to build a program that will ensure dischargers meet the state's water quality standards and protect water quality. The program will be phased in over four years and Region 10 will continue to provide technical assistance.

Region 10 Participates in Regional Tribal Operations Committee Quarterly Meeting in Juneau, AK
The Region 10 Tribal Operations Committee will meet from June 5th-7th in Juneau, Alaska. Agenda topics include updates from EPA headquarters and Region 10 leadership on water quality standards and fish consumption rates, drinking water and the Backhaul Alaska Pilot Project. In addition, Tribal Operations Committee members will provide direct report outs to EPA leadership on environmental issues and concerns. Region 10's Deputy Regional Administrator and Tribal Policy Advisor will attend as well as several staff members.

EPA Leads Food Recovery Summit at CenturyLink Field in Seattle
On June 7th, Region 10 staff will facilitate a half-day food recovery summit at CenturyLink Stadium. The summits hosts hotel and restaurant chefs from King County and representatives from food recovery organizations across the state who will share best practices and opportunities for food recovery within the hospitality sector. The event is being hosted by the Seattle Seahawks, who are active participants in both EPA's Food Recovery Challenge and EPA's WasteWise partnership program. An audience of over 100 hotel and restaurant chefs, food and beverage directors, and sustainability managers are expected.

Region 10 Hosts Meeting of the Puget Sound Federal Task Force (WA)
On June 7th, Region 10 Administrator Chris Hladick will host two Puget Sound Federal Task Force meetings: one with regional federal leaders and a second with federal leaders and western Washington tribal leaders. The purpose of the regional federal leaders meeting is to report out on Puget Sound Action Plan accomplishments since Jan. 2017, and plan for an upcoming Federal Task Force leadership meeting later this summer in Washington, D.C. The joint federal/tribal leaders meeting is being convened to discuss updates on the Western Washington Treaty Rights at Risk issues, report out on Puget Sound Federal Task Force Action Plan accomplishments as they relate to tribal priorities, and provide an opportunity for new tribal and federal leaders to coordinate and strategize on how best to work together.

Office of Administration and Resources Management

Hot Topics:

Workgroups Established to Implement New Executive Orders
On May 25, 2018, President Trump issued three new executive orders impacting: 1) collective bargaining; 2) union official time and space; and 3) employee accountability. OARM has established three agency-wide workgroups to evaluate the executive orders and their impact on EPA, and develop recommended action plans for EPA compliance with the executive orders.

Employee Viewpoint Survey Results
As of May 29, 2018, EPA's agency-wide Employee Viewpoint Survey response rate was 36%. The government-wide response rate is 26%. Employees are encouraged to complete the survey by June 12, 2018.

Upcoming Major Decisions and Events:

None.

Office of Air and Radiation

Hot Topics:

- **Tracking SIP Actions:**
  - Total Number of SIPs submitted to Regions in FY 2018: 199
  - Total Number of SIP Submittals with Final Action taken by the Regions in FY 2018: 157
  - Total Number of Pending SIPs: 765

- **Packages at OMB for Review:**
  - Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Reconsideration (Proposed Rule)
  - NESHAP: Surface Coating of Large Appliances; Printing, Coating, and Dyeing of Fabrics and Other Textiles; and Surface Coating of Metal Furniture RTR (Proposed Rule)
  - Protection of Stratospheric Ozone: Revisions to the Refrigerant Management Program's Extension to Substitutes (Proposed Rule)
  - Renewable Fuel Standard Program: Standards for 2019 and Biomass-Based Diesel Volume for 2020 (Proposed Rule)

- **Packages that will move soon to OMB for Review:**
  - Repeal of Emission Requirements for Glider Vehicles, Glider Engines, and Glider Kits (Final Rule)

- **Packages that will move soon to Signature:**
  - Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings (Withdrawal of Proposed Rule)

Upcoming Major Decisions and Events:

Ozone Transport Commission (OTC)
Next Wednesday, Bill and Clint will be attending the OTC Executive Session in Baltimore. (The OTC is a multi-state organization created under the Clean Air Act that is responsible for advising EPA on transport issues and for developing and implementing regional solutions to ground-level ozone issues in the Northeast and Mid-Atlantic regions).

Office of Chemical Safety and Pollution Prevention

IMPORTANT DEADLINES

Row	Determination Type	Pending on 5/29/2018	Determinations Completed[1] as 5/29/2018	Determinations Posted on the Website as of 5/29/2018[6]
1	# of "not likely" determinations	**1**	**122**[4]	**122**[4]
2	# of §5(e) Orders signed by both EPA and the submitter	-	**400**	**399**
3	# of §5(e) Orders signed by EPA and awaiting submitter signature	**41**	-	-
4	# of non-Order SNURs/"not likely" determinations	**0**	**0**	**0**
5	# of cases in post-FOCUS final determination development[5]	**318**[3, 5]	-	-
6	# of cases flagged for in-depth review	**43**	-	-
7	# of PMNs, SNUNs and MCANs awaiting FOCUS (within 90-day review)	**30**	-	-
8	# of LVE/LOREX exemption grants	-	**602**	**597**
9	# of LVE/LOREX exemption denials	-	**121**	**120**
10	**Total number of cases**	**433**	**1245**	-
11	Normal active workload for the New Chemicals Program	300	-	-
12	Number of cases undergoing testing or data development by submitter	74[3]	-	-
13	**Backlog**[2]	59	-	-

[1]"Determinations Completed" means that EPA has completed its reviews on these cases and that final determinations have been made by EPA under TSCA section 5(a)(3).

[2] (Total number of cases) – (Normal active workload for the New Chemicals Program) - (Number of cases undergoing testing or data development) = Backlog

[3] Of these cases, approximately 72 are "active" lung toxicity cases that are suspended while submitters either conduct or are deciding whether to conduct testing to develop data on pchem properties, exposures and toxicity.

[4] "Not Likely" determinations are not posted until the final signed determination document is prepared and has been shared with submitter.

[5] These cases are those for which Post-FOCUS work is underway to develop: not likely determinations; non-Order SNURS coupled with not likely determinations; or section 5(e) or 5(f) Orders. When the OPPT Office Director decides which of these regulatory paths to follow, the case is moved to: Row 3 when the section 5(e) or 5(f) Order is sent to the submitter for signature; Row 4 when the SNUR is published and the not likely determination document is signed; and Row 1 when the determination document is sent to the OPPT OD for signature.

[6] These are all only final determinations posted on the web: grants and denials.

Hot Topics:

Problem Formulations for First 10 Chemicals Selected for Risk Evaluation under Toxic Substances Control Act (TSCA)

On June 1, OCSPP released the problem formulation documents for public comment on the first 10 chemicals selected for risk evaluation under the amended TSCA. Asbestos, methylene chloride, 1,4-dioxane, tricholoroethylene, and cyclic aliphatic bromide cluster (HBCD) are among the first of the chemical problem formulations that were released. EPA intends to finalize these ten risk evaluations by December 2019. OCSPP

is also releasing a systematic review approach to share with the public the methodology that the TSCA program will use to ensure that the best available science is relied upon in these and other risk evaluations.

EPA Announces a Significant New Use rule (SNUR) for Certain Uses of Asbestos
EPA is proposing a SNUR for certain uses of asbestos (including asbestos-containing goods) that, when final, will require manufacturers and importers to notify EPA before starting or resuming manufacturing, importing or processing of asbestos.

Upcoming Major Decisions and Events:

The Full State FIFRA Issues Research and Evaluation Group (SFIREG) Meeting
On June 4-5, Ed Messina, Acting Deputy Director of the Office of Programs and several staff will present at the Full State FIFRA Issues Research and Evaluation Group (SFIREG) meeting on various topics, including Cooperative Federalism – Implications for State Pesticide Regulatory Programs, Pollinator Protection Activities, Dicamba, and ESA BiOp Update.

12th Antimicrobial Workshop
On June 7-8, the Office of Pesticide Program's will host the 12th Annual Antimicrobial Workshop at the Renaissance Arlington Capital View Hotel in Arlington, VA. Topics planned for discussion include, the Antimicrobial Testing Program, Updates to Electronic Submission Portal, Emerging Viral Pathogens, Update on 810 Guidelines, SmartLabel and e-CSF, and Registration Review Updates.

Office of the Chief Financial Officer

Hot Topics:

- EPA has received a total of $3.2 million from the Federal Emergency Management Agency to support FEMA's response to the Lava Flows/Volcano Eruption in Hawaii.
- OCFO continues to coordinate with the agency to review responses to House Appropriations Committee's FY 2019 budget hearings Questions for the Record (QFRs) and is reviewing the Senate Appropriations Committee's hearing transcript. OCFO expected SAC QFRs to arrive this week but those QFRs have not yet arrived.
- The HAC Full Committee mark-up of EPA's FY 2019 appropriations bill is scheduled for June 6. SAC Subcommittee and Full Committee markups are scheduled for the week of June 11.

Upcoming Major Decisions and Events:

- NPM feedback on draft materials for the FY 2018 second quarter Administrator's Performance Review were due to OCFO May 31. OCFO will consolidate and vet through the COO. The Quarterly Performance Review is scheduled for June 19 from 3-5 pm and includes all AAs and RAs.
- OPA is reviewing EPA's final draft FY 2018 second quarter Agency Priority Goal (APG) Action Plans, which address minor OMB comments. Once OPA approval is received, OCFO will provide final draft plans to OMB to meet its June 8 deadline. OMB target date for posting second quarter updates on publicly available website is June 14.

Other

- The OMB/EPA Strategic Review meeting is set for June 19 from 1-2:30 pm to discuss results of EPA senior leader assessments of progress toward the Strategic Plan, including risks to achieving strategic objectives, and management priorities focused on EPA Lean Management System deployment. OCFO is working with OMB and the Deputy Administrator's office to finalize meeting logistics. In addition to the Deputy Administrator, expected EPA participants include the COO, CFO, and AAs/DAAs (or equivalent) for OCIR, OP, OGC, OARM, and OITA.

Office of Congressional and Intergovernmental Relations

Hot Topics:

June 7 - House Energy and Commerce Committee, Subcommittee on Energy will hold a hearing on: Hydropower Licensing and Water Quality Certification under CWA 401
(Witness: John Goodin, OW) and other agencies, 11 am, 2123 Rayburn

Upcoming Major Decisions and Events:

- **June 4** – Small Communities Advisory Subcommittee will have an introductory teleconference Monday at 2pm. Ken Wagner, Senior Advisor to the Administrator for Regional and State Affairs is scheduled to speak with the newly appointed and current members.
- **June 5** – Notification of Idaho NPDES transfer of authority
- **June 6**- Quarterly Outreach meeting with Intergovernmental Associations will feature an introduction of EPA Deputy Administrator Andrew Wheeler, and an opportunity for brief engagement with the representatives of attending Intergovernmental Associations. Part II of the meeting will focus on "The Federal Strategy to Reduce Childhood Lead Exposure." Dr. Hayley Hughes, EPA National Lead Coordinator, Office of the Administrator, will provide updates, and engage in dialogue with the group.
- **June 6** – House Energy and Commerce member briefing on PFAS four-step action plan w/OW, OLEM, OCSPP, ORD
- **June 6&7** – Senator McCain, Rio Salado Federal Partners Tour, Tempe AZ
- **June 8** - US Conference of Mayors 86th Annual Meeting in Boston, MA
- **June TBD** – Senator Baldwin staff call on PFAS actions w/OW
- **June TBD** – Congressman Latta staff and HEC staff briefing on HABs in drinking water
- **June TBD**- Congressman Doyle staff briefing re: PFAS actions
- **TBD** – Cong. Peters (CA) TA re Point Loma WWTP legislation w/OW, OGC, R9
- **TBD** – Sen. Tester (MT) staff briefing on Elk River Watershed w/OW, R8
- **TBD** – Sen. Isakson (GA) staff briefing on new chemicals process w/OCSPP
- **TBD** – Approps staff briefing on PRIA fees w/OCSPP, OCFO
- **TBD** - SEPW/HEC staff briefing on TSCA first 10 chemical problem formulations w/ OSCPP

Office of Enforcement and Compliance Assurance

Hot Topics:

Construction Company Pleads Guilty for Not Following Lead Rules
On May 22, 2018, Bitner Brothers Construction, Inc. pleaded guilty in the Middle District of Pennsylvania on one count of violating TSCA and one count of Aiding and Abetting. Both Bitner Brothers Construction and owner Charles H. Bitner, Jr. will forfeit their lead certification licenses. Bitner Brothers Construction, Inc. is in the business of conducting residential and commercial renovations, repairs, and painting. Bitner Brothers did not follow required work practice standards during the replacement of windows in an apartment complex located in Harrisburg, Pennsylvania in early 2017.

Five Pennsylvania Men Charged with Conspiring to Defraud the U.S. and Violate the Clean Air Act
On May 25, 2018, Gavin Rexer, Dennis Paulhamus, Timothy Sweitzer, Joseph Powell, and John Joseph were charged with conspiring to impede the lawful functions of the EPA and DOT and to violate the Clean Air Act. Rexer, Powell, and Joseph were employees of Rockwater Northeast, a company that serviced the fracking industry. In the course of their employment, they conspired to modify the emissions systems on approximately 30 Rockwater heavy-duty diesel trucks by using "defeat devices." The defeat devices were obtained from Paulhamus and Sweitzer and their purchases were concealed in Rockwater's books and records by mislabeling them as exhaust systems. The conspirators also are accused of taking the modified commercial motor vehicles to state approved inspection stations, including Sweitzer's Garage, to pass federally regulated commercial motor vehicle inspections falsely.

Army Pays Stipulated Penalty to Resolve Violations at the Umatilla Army Depot
On May 14, 2018, the United States Army paid a stipulated penalty of $125,000 to EPA to resolve violations of the CERCLA Federal Facilities Agreement (FFA) for the Umatilla Army Depot after receiving a Congressional appropriation for the penalty. On July 14, 2016, EPA Region 10, the Army, and the Oregon Department of Environmental Quality signed a settlement agreement to resolve violations set forth in a November 2, 2015, Notice of Violation. The Army's failed to comply with several remedial action requirements contained in the Workplan for Munitions and Explosives of Concern. The settlement agreement included a new schedule and technical approach for the work remaining to be done at Umatilla along with an agreement that the Army would pay a stipulated penalty of $125,000 after it obtained Congressional authorization to pay the penalty.

Upcoming Major Decisions and Events:

On June 6, 2018, OECA AA Susan Bodine, PDAA Larry Starfield, and DAA Patrick Traylor will travel to EPA Region 7 to meet with the RA/DRA and senior enforcement managers in Region 7 to discuss enforcement and compliance priorities and issues.

On June 5, 2018, OECA DAA Patrick Traylor will join other EPA leaders in New Orleans, Louisiana to discuss hurricane preparedness for 2018, including lessons learned from recent natural disasters.

Office of Environmental Information

Hot Topics:

E-Enterprise for the Environment Launches Be Well Informed – a State-developed Shared Service
Brief description: On June 6, private well owners in New Hampshire and Wyoming will have a new web-based tool to help them understand their well water test results. Originally built by the New Hampshire Department of Environmental Services, in collaboration with their Department of Information Technology, OEI adapted the tool to enable states, tribes, and territories to use this capability to develop their own tools for private well owners with minimal development costs.
Who benefits or cares: Private well owners in participating states, Commissioners with well water programs, and state environmental agencies who are responding to citizen inquiries regarding their well water.
Why this is important: The tool demonstrates how collaborative innovation and E-Enterprise can:

- Reduce costs to E-Enterprise partners (states, tribes and EPA).
- Provide consistent, timely, and actionable information to citizens.

Additional information:

- Massachusetts, Minnesota, Vermont and Michigan are working towards adopting the tool; other states and tribes have expressed interest.
- This work was partially supported by E-Enterprise funding provided by OCFO.
- As E-Enterprise resources allow, OEI will work with other states/tribes/territories to support this shared service.

Upcoming Major Decisions and Events:

None.

Office of General Counsel

Hot Topics:

- *Charles A. Folsom v. USACE*, No. 4:17-cv-3143 (D. Neb.). New development: On May 30, Charles Folsom, a Nebraska landowner, filed a notice of appeal to the US Court of Appeals for the Eighth Circuit challenging a decision from the US District Court for the District of Nebraska granting EPA's motion to dismiss his challenge to pre-enforcement activities by EPA and the Corps regarding the placement of fill into the Elkhorn River. EPA sent Mr. Folsom a proposed compliance order and invited him to negotiate and Mr. Folsom declined and sued EPA and the Corps to enjoin them from bringing any enforcement action. The District Court dismissed the complaint.
- *Ctr. for Envtl. Health v. Pruitt,* No. 3:18-cv-03197 (N.D. Cal). New development: On May 30, three NGOs filed a complaint against EPA and FWS for failing to comply with section 7 of the ESA with respect to the registration or reregistration of 21 pesticide products containing the active ingredient malathion. Plaintiffs assert that EPA and FWS have failed to meet their substantive duty to ensure that the malathion products do not jeopardize endangered and threatened species, and that EPA and FWS's agreement to indefinitely extend the current ESA consultation on malathion is unlawful.
- *Ctr. For Biological Diversity v. EPA,* No. 1:18-cv-1219 (D.D.C.). New development: On May 25, Plaintiff filed a FOIA lawsuit alleging that EPA has not responded to five FOIA requests and one FOIA fee waiver administrative appeal. The FOIA requests sought all communications to or from Administrator Pruitt including emails, text messages, and phone logs generally, and on a variety of topics including ethics, "sue and settle," encrypted messaging and email records management.
- *Husch Blackwell v. EPA*, No. 1:18-cv-1213 (D.D.C.). New development: On May 25, the law firm, Husch Blackwell, filed a FOIA lawsuit alleging that EPA failed to respond to a FOIA request within the statutory time frame for a request seeking certain communications involving Jess Rowland and glyphosate or Proposition 65.
- *Sanitary Bd. of the City of Charleston, W. Virginia v. Pruitt,* No. 2:16-cv-03060 (S.D.W. Va.). New development: On May 24, Plaintiff filed a notice of appeal to the US Court of Appeals for the Fourth Circuit challenging two decisions from the US District Court, prompted by EPA's disapproval of a site-specific copper criterion that was submitted by WVDEP at Plaintiff's request. Plaintiff is challenging the District Court's rulings that (1) EPA did not have a mandatory duty to approve the site-specific criterion and (2) Plaintiff lost standing to challenge the disapproval when WVDEP issued the facility a new permit, which did not impose any copper limits on its discharge.
- *Dine' Citizens Against Ruining the Env't v. EPA*, No. 18-71481 (9th Cir.). New development: On May 23, five NGOs filed a petition for writ of mandamus asking the Ninth Circuit to compel EPA Region 9 to take final action on a Clean Water Act NPDES permit renewal application for the Four Corners Power Plant located on the Navajo Nation, near Farmington, New Mexico. According to the Petition, the coal-fired power plant has been operating under an expired administratively continued permit since 2006.

Upcoming Major Decisions and Events:

6/12 Hearing on EPA's motion to stay in *Ass'n of Irritated Residents v. EPA*, a deadline suit regarding EPA's failure to take action on the San Joaquin Valley Unified Air Pollution Control District's 2016 SIP addressing nonattainment requirements for the 2008 8-Hour Ozone Standard.

Office of International and Tribal Affairs

Hot Topics:

Tijuana Spill
OITA met with the new U.S. Consulate General to Tijuana to discuss the Tijuana spill, International Boundary and Water Commission (IBWC), North American Development Bank and U.S.-Mexico Border Program. At our urging, the Consulate General has agreed to raise the Tijuana spill and funding for Tijuana infrastructure improvements with the local and national governments in Mexico. She also agreed to look into IBWC funding mechanisms and operations at the State Department.

Columbia River Treaty
The formal negotiations between the U.S. and Canada for the modernization of the Columbia River Treaty commenced this week. The U.S. negotiation team consists of the State Department, Interior/NOAA, and Bonneville Power. OITA and Region 10 met with the State Department to discuss the role of EPA and tribes in the negotiations, and State has agreed to involve EPA in the USG strategy sessions and ensure meaningful engagement with the tribes.

Upcoming Events and Decisions:

G7 Deputies Meeting
A Deputies Meeting will be held on June 1 to discuss the upcoming G7 Leaders' Summit in Charlevoix, Quebec on June 8-9, which includes Climate Change, Energy and Oceans session.

Premier of Saskatchewan
The Administrator will be meeting with the Premier of Saskatchewan, Canada, on June 6 to discuss Canada-U.S. environmental regulation.

North American Development Bank
OITA will be meeting with the North American Development Bank on June 4 to discuss current activities and upcoming Board of Directors meeting in Mexico.

Canadian Environmental Assessment Agency
The Canadian Environmental Assessment Agency will be meeting with OP and OITA on June 6/7 to discuss the EIA process, including transboundary impacts and tribal engagement.

Office of Land and Emergency Management

Hot Topics:

- **Coal Combustion Residuals (CCR)**. (see below)

- **Clean Air Act 112(r) Risk Management Program (RMP) Reconsideration NPRM.** The proposed rule was published in the FR on May 30. A public hearing is scheduled for June 14. The public comment period ends July 30, 2018.

- **Ongoing major Superfund NPL sites** (including Colorado Smelter, East Chicago, West Lake, Bonita Peak, Hudson River, Portland Harbor, Mississippi Phosphates, Oak Ridge, Edwards AFB, Berry's Creek, American Cyanamid).

- **CERCLA 108(b) Financial Assurance – Next Three Sectors**. We are working with OGC, OP, and the AO to plan our approach to the next three sectors.

- **PFOA and PFAS.**
  - Working with OCIR, OW, and others, we are preparing for a briefing on PFAS with House Energy and Commerce members.
  - We are working with ORD and OW to develop groundwater cleanup recommendations for PFOA and PFOS.
  - OLEM is working with the AO, OGC, OECA and other AAships to look at available statutory mechanisms for PFOA and PFOS to be "hazardous substances" under CERCLA.

- **Emergency Response.** Region 9 emergency response and the national Environmental Response Team are part of the inter-governmental effort addressing volcano activity in Hawaii. OAR and ORD are assisting OLEM and Region 9 with public messaging related to acute and chronic risk from exposure to volcanic gases. Current staffing is 24.

Upcoming Major Decisions and Events:

- **Definition of Solid Waste Vacatur.** This was published in the FR on May 30, 2018.

- **Coal Combustion Residuals**.
  - We plan to get the proposed rule to OMB next week and anticipate signature on June 14 to align with the approval of Oklahoma's CCR permitting program.
  - Georgia submitted its CCR permit program application to EPA. It is undergoing review.

- **E-Manifest**. We anticipate issuing a press release on June 29, 2018.

- **Hazardous Waste Pharmaceuticals Final Rule**. We will be briefing the AO and OP in early June.

- **Hazardous Substances Spill Prevention Proposed Rule**. We anticipate OMB clearance by June 8 to allow for signature by June 15.

Office of Policy

Upcoming Major Decisions and Events:

Meeting with Canada
On June 6-7, the Office of Federal Activities will join OITA, the State Dept., and CEQ in a meeting with representatives from the Canadian government to discuss best practices for Environmental Impact Assessment and transboundary issues.

Community Assistance Announcement
In early June, the Office of Community Revitalization plans to announce six communities selected for assistance through the Healthy Places for Healthy People program, a federal initiative that works with healthcare facilities to protect the environment, improve public health, and support reinvestment in neighborhoods.

Number of Actions to OFR this Year:

- Signed by Regions:
  - Notices: 40
  - Proposed Rules: 123
  - Direct Final Rules: 8
  - Withdrawal of Proposed Rule: 1
  - Withdrawal of Direct Final: 4
  - Final Rules: 101
- Signed by HQ:
  - Notices: 204
  - Proposed Rules: 32
  - NPRM Extension: 1
  - Withdrawal of Direct Final: 1
  - Interim Final: 1
  - Final Rules: 64

Number of Actions to OFR this Week (May 25 – May 31):

- Signed by Regions:
  - Notices: 4
  - Proposed Rules: 13
  - Direct Final Rules: 0
  - Withdrawal of Proposed Rule: 0
  - Withdrawal of Direct Final: 1
  - Final Rules: 5
- Signed by HQ:
  - Notices: 11
  - Proposed Rules: 1
  - NPRM Extension: 0
  - Withdrawal of Direct Final: 0
  - Interim Final: 0
  - Final Rules: 5

Active Interagency Reviews from OMB	
Title	**OMB Due Date**
DOL/MSHA RFI: "Retrospective Study of Respirable Coal Mine Dust Rule"	05/30/2018
FAR Case 2017-014 ANPRM: "Federal Acquisition Regulations: Use of Acquisition 360 to Encourage Vendor Feedback"	06/01/2018

USDA ANPRM: "Oil and Gas Resources"	06/01/2018
USDA ANPRM: "Locatable Minerals"	06/01/2018
DOI & DOC NPRM (Pass-back): "Endangered and Threatened Wildlife and Plants; Revision of Regulations for Interagency Cooperation"	06/01/2018

Documents Submitted to OFR from May 23 - 29, 2018		
FRL	**Title**	**Date Submitted to OFR**
9978-93-Region 4	Air Plan Approval and Air Quality Designation; SC; Redesignation of the Greenville-Spartanburg Unclassifiable Area	5/29/2018
9978-92-Region 4	Air Plan Approval; South Carolina; Regional Haze Plan and Prong 4 (Visibility) for the 2012 PM2.5, 2010 NO2, 2010 SO2, and 2008 Ozone NAAQS	5/29/2018
9978-90-Region 4	Air Plan Approval and Air Quality Designation; AL; Redesignation of the Etowah County Unclassifiable Area	5/29/2018
9978-72-Region 8	Interstate Transport Prongs 1 and 2 for the 2010 Sulfur Dioxide (SO2) Standard for Colorado, Montana, North Dakota, South Dakota and Wyoming	5/29/2018
9974-26-Region 8	North Dakota Final Authorization and Incorporation by Reference of Approved State Hazardous Waste Management Program	5/29/2018
9978-73-OEI	Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting	5/29/2018
9978-77-ORD	Ambient Air Monitoring Reference and Equivalent Methods; Designation of One New Reference Method	5/29/2018
9977-72-OAR	Additional Air Quality Designations for the 2015 Ozone National Ambient Air Quality Standards	5/29/2018
9978-94-Region 4	Approval of TN Plan for Control of Emissions from Commercial and Industrial Solid Waste Incineration Units	5/25/2018
9978-87-Region 5	Air Plan Approval; Ohio; Cleveland, PM2.5 Attainment Plan	5/25/2018
9978-86-OAR	Proposed Information Collection Request; Comment Request on Two Proposed Information Collection Requests	5/25/2018
9978-80-Region 7	Delegation of Authority to the States of Iowa; Kansas; Missouri; Nebraska; Lincoln-Lancaster County, NE; and City of Omaha, NE, for New Source Performance Standards (NSPS), National Emission Standards for Hazardous Air Pollutants (NESHAP) Including Maximum Achievable Control Technology (MACT) Standards	5/25/2018
9978-56-Region 3	Approval and Promulgation of Air Quality Implementation Plans; Maryland; Continuous Opacity Monitoring Requirements for Municipal Waste Combustors	5/25/2018
9977-76-OCSPP	Pesticide Emergency Exemptions; Agency Decisions and State and Federal Agency Crisis Declarations	5/25/2018
9977-62-OCSPP	Defensin Proteins Derived from Spinach in Citrus Plants; Temporary Exemption from the Requirement of a Tolerance	5/25/2018
9976-99-OCSPP	Product Cancellation Order for Certain Pesticide Registrations and Amendments to Terminate Uses	5/25/2018
9978-74-Region 4	Public Water System Supervision Program Revision for the Commonwealth of Kentucky	5/25/2018

9978-82-Region 9	Air Quality State Implementation Plans: Arizona; Approval and Conditional Approval of State Implementation Plan Revisions; Maricopa County Air Quality Department; Stationary Source Permits	5/25/2018
9977-80-Region 8	National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Davenport and Flagstaff Smelters Superfund Site	5/25/2018
9978-81-Region 9	Approval and Promulgation of Air Quality Implementation Plans; Nevada; Rescission of Regional Haze Federal Implementation Plan for the Reid Gardner Generating Station	5/25/2018
9978-79-Region 7	Approval of Nebraska Air Quality Implementation Plans; Title 129, Chapter 20, Particulate Emissions; Limitations and Standards	5/24/2018
9978-78-Region 7	Approval of Missouri Air Quality Implementation Plans; Infrastructure SIP Requirements for the 2012 Annual Fine Particulate Matter (PM2.5) National Ambient Air Quality Standard Interstate Transport	5/24/2018
9978-27-Region 1	Air Plan Approval; New Hampshire; Nonattainment Plan for the Central New Hampshire Sulfur Dioxide Nonattainment Area	5/24/2018
9978-26-Region 1	Air Plan Approval; Connecticut; Volatile Organic Compound Emissions from Consumer Products and Architectural and Industrial Maintenance Coatings	5/24/2018
9977-56-OLEM	Response to Vacatur of Certain Provisions of the Definition of Solid Waste Rule	5/24/2018
9978-49-OECA	Proposed Information Collection Request; Comment Request; See Item Specific ICR Titles Provided in the Text	5/24/2018
9974-81-OEI	NESHAP for Beryllium Rocket Motor Fuel Firing (Renewal)/ICR No.1125.0	5/24/2018
9975-90-OEI	NSPS for Glass Manufacturing Plants (Renewal)/ICR No.1131.12	5/24/2018
9978-66-Region 5	Adequacy Status of the Indiana Portion of the Chicago-Naperville, IL-IN-WI Area for the Submitted 2008 Ozone Standard Fifteen Percent Rate of Progress Plan for Transportation Conformity Purposes	5/24/2018
9978-61-Region 5	Air Plan Approval; Michigan; Regional Haze Progress Report	5/23/2018
9978-59-Region 4	Air Plan Approval and Air Quality Designation; KY; Redesignation of the Kentucky Portion of the Louisville Unclassifiable Area	5/23/2018
9978-57-Region 3	Approval and Promulgation of Air Quality Implementation Plans; Virginia; Emissions Statement Rule Certification for the 2008 Ozone National Ambient Air Quality Standard	5/23/2018
9978-18-Region 9	Approval of California Air Plan Revisions; Butte County Air Quality Management District; Stationary Source Permits	5/23/2018
9976-24-OCSPP	Agency Information Collection Activities; Proposed Renewal of Several Currently Approved Collections (EPA ICR Nos. 2491.04 and 2475.03); Comment Request	5/23/2018
9978-69-OEI	EPA's In-Use Vehicle and Engine Testing Programs, ICR No. 0222.11	5/23/2018
9978-68-OEI	NESHAP for Group I Polymers and Resins (Renewal)" ICR No. 2410.04	5/23/2018
9978-60-OEI	NESHAP for Pharmaceuticals Production (Renewal)/ICR No. 1781.08	5/23/2018

9976-72-Region 6	Clean Air Act Operating Permit Program; Petitions for Objection to State Operating Permit for ExxonMobil Corporation, ExxonMobil Baytown Refinery, Harris County, Texas	5/23/2018
9978-58-ORD	EPA Board of Scientific Counselors Notice of Charter Renewal	5/23/2018
9978-53-OLEM	Agency Information Collection Activities; Proposed Collection; Comment Request; Continuous Release Reporting Regulations (CRRR) under CERCLA 1980 (Renewal); EPA ICR No. 1445.13, OMB Control No. 2050-0086	5/23/2018
9978-54-OW	Extension of the Application Deadline Date for Credit Assistance under the Water Infrastructure Finance and Innovation Act (WIFIA) Program	5/23/2018
9978-75-Region 10	Air Plan Approval; Washington; Regional Haze Progress Report	5/23/2018

Office of Research and Development

Hot Topics:

***Fentanyl Fact Sheet* for On-Scene Coordinators**
Nearly half (over 19,000) of the opioid-related deaths in the U.S. in 2016 involved fentanyl. EPA and state-level responders have emphasized the lack of comprehensive information on the detection, sampling, analysis and decontamination for the fentanyl class of synthetic opioid chemical compounds. ORD partnered with Office of Emergency Management's CBRN Consequence Advisory Division and Environmental Response Team, Region 5, and others to develop *the Fentanyl Fact Sheet*. It is living document that compiles current, publicly-available information for use by EPA OSCs, and may also be useful to local/state first responders such as EMT, hazmat, and law enforcement. ORD's research underway on fentanyl sampling methods and decontamination will strengthen the fact sheet over time.

Technical support on Tularemia to the Kentucky Department of Public Health
ORD is supporting the Kentucky Department of Public Health in their response to a tularemia outbreak in Butler County, Kentucky. The causative agent of tularemia, *Francisella tularensis*, is classified as a Tier 1 Select Agent by the U.S. government due to its low infectious dose, ease of spread by aerosol, and high virulence. This outbreak has affected cottontail rabbits, Beagle handlers, and Beagle dogs residing in a 240-acre beagle field trial ground. Humans can be infected with the organism by contact with infected animals or vectors. To better understand the cause of the outbreak, ORD is guiding Kentucky Department of Public Health on sampling and analysis of *Francisella tularensis* in environmental samples, and providing advice on collection and stabilization of water samples and possible causes of the outbreak.

IRIS Assessment Released for Review
On May 30th, the draft assessment for hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX) was released for post-peer review Interagency and Agency review.

Upcoming Major Decisions and Events:

We look forward to hosting OCSPP leadership in RTP on June 8 where we will discuss ORD data, methods, and tools being developed to support TSCA prioritization. On June 5th ORD staff will kick off summer with an evening of baseball at National's Park.

Science Advisory Board Meeting
On June 1st, ORD will provide an update on IRIS at the Science Advisory Board meeting. ORD will also present an overview of lead science that highlights seven success stories. Other participants and presenters include the Office of the Administrator on the Federal Lead Strategy, Office of Water, Office of Land and Emergency Management, and Office of Chemical Safety and Pollution Prevention.

Office of Water

Hot Topics:

Georgia Nonpoint Source Pollution Control Program
Today, Dave Ross co-signed a joint EPA/NOAA Federal Register Notice announcing the agencies' intent to fully approve the Georgia Coastal Nonpoint Pollution Control Program. The notice invites public comment on the agencies' proposed finding that Georgia has satisfied all conditions on the 2002 approval of the State's coastal nonpoint pollution control program. The Coastal Zone Act Reauthorization Amendments directs states and territories with coastal zone management programs previously approved under Section 306 of the Coastal Zone Management Act to develop and implement coastal nonpoint programs, which must be submitted to the federal agencies for approval. The notice will be sent to NOAA next for signature. Once published, the notice will open a 30-day public comment period.

WIFIA
As part of OW's enhanced outreach strategy to promote the 2018 Notice of Funding Availability (NOFA) opportunity, this week, the WIFIA program hosted the WIFIA Letter of Interest Submission and Selection Process Question and Answer Session. More than 70 people participated in the event. The next webinar, scheduled for June 4, will provide an overview of the WIFIA program and the 2018 selection round. In addition, OW, working with OPA, provided the regional public affairs directors with a "pitch" packet to use with local media outlets as well as key messages to fold into senior leadership speeches. Tomorrow, the WIFIA staff will present at the New England Environmental Business Council Infrastructure Workshop: Update and Overview of WIFIA Water Infrastructure Loan Program.

Environmental Financial Advisory Board (EFAB) Membership Package
This week, the EFAB's 2018 Official Membership Package was approved and is moving forward for the Administrator's signature. The package includes a new recommended chair, 4 new EFAB member appointments, and 3 departures. The term for appointees will run for a period of two years beginning June 15.

Waterkeeper II Steam Electric FOIA
This week, OW provided the May interim release for this FOIA to the requestor. The EPA was under court order to complete this FOIA by May 31st, however, the court granted an extension of that deadline to June 21, 2018.

Upcoming Major Decisions and Events:

HEC Hearing
Next week, John Goodin, Acting Director for the Office of Wetlands, Oceans and Watersheds, will testify before the House Committee on Energy and Commerce (HEC), Energy Subcommittee. He will testify to the EPA's role on the CWA section 401 state delegated authority and water quality certification process in relation to the non-federal hydropower licensing process. The panel is comprised of officials from FERC, NOAA, FWS, and USACE. The hearing is open to press.

EPA-National Tribal Water Council Meeting
Next week, Benita Best Wong will provide the opening remarks for the Council meeting and discuss with members' water issues in Indian country. This meeting is closed to press.

Public Meeting on Unregulated Contaminants in Drinking Water
Next week, the EPA will host an all-day public meeting and webinar at EPA-Cincinnati. Approximately 300 participants have registered for the meeting which will include presentations from the Technical Support Center in Cincinnati and ORD on the EPA drinking water method development and include discussion with stakeholders on innovative analytical testing procedures for unregulated contaminants.

Region 1

Hot Topics:

Parties Reach Significant Agreement in Principle on Priority Superfund Site
EPA, the State of Rhode Island, and Black & Decker have reached a mediated agreement in principle on the Consent Decree (CD) and Statement of Work (SOW) at the Centredale Manor Site in North Providence, RI. EPA will likely sign in early June. The CD will be lodged with the Court in mid-June. Under the terms of the CD, the PRPs will begin performance on the RD upon lodging. This Site is on Administrator Pruitt's list of sites targeted for immediate, intense action.

NH MS4 Permit Mediation Kicks-off
This week, mediation began among the appellants of the NH MS4 general permit for small municipalities. While the state of New Hampshire is not a party to the litigation, Region 1 secured the agreement of all parties to the state's participation in the mediation. Mediation for the Massachusetts MS4 general permit, which started last week, continues.

Lead Paint Removal Contractors Receive Notice of Upcoming Lead Inspections
Region 1 began outreach to contractors located in our two focus communities of Portsmouth, NH and Portland, ME. An initial mass mailing of 171 letters, including 23 to those whose lead removal firm certification has expired were sent to Portsmouth contractors. The letters provided information on EPA's initiative, lead-based paint rules, lead in drinking water, and on how to identify EPA accredited trainers in their area. A similar mass mailing to Portland contractors is expected to go out next week. Region 1 is coordinating these efforts with local and state officials as well as community groups.

Upcoming Major Decisions and Events:

Charles River (Massachusetts) Receives an A- in Annual Water Quality Report Card Announcement
On June 1, Region 1 will announce its 23rd annual grade for water quality in the Charles River. The grade of A- reflects 2017 data showing that the river met boating standards 95% of the time and swimming standards 72% of the time. This is only the second time that the Charles has achieved a grade this high.

RA Dunn, Erin Chancellor and Steven Cook to meet with concerned citizens at Coakley Superfund Site
On June 4, RA Dunn, Adviser Erin Chancellor and Deputy AA Steven Cook will visit the site and meet with Community Activist Jillian Lane and concerned neighborhood citizens. This visit is a follow-up to Albert Kelly's commitment to Jillian Lane that he would visit the site.

RA Dunn and Erin Chancellor to participate in two New Bedford Harbor events with Mayor Mitchell
On June 5, RA Dunn and Adviser Erin Chancellor will participate in an onsite celebration of the completion of the Pierce Mill Cove cleanup and the reopening of Riverside Park. Following the celebration, they will participate in a roundtable with Mayor Mitchell on his plans for economic growth and development of the New Bedford Harbor. MassDEP and USACE will also be in attendance.

Region 2

Hot Topics:

Consent Order with National Grid at Gowanus Canal Superfund Site
On 5/24 Region 2 finalized this consent order, which provides for extensive cleanup work with an estimated value of about $100 million. Under the order National Grid will construct a sealed barrier wall to contain coal tar migration from its former Fulton Manufactured Gas Plant site; remove coal tar at two properties following their acquisition by New York City for construction by the City of an 8-million gallon CSO retention tank (required under the 2013 Record of Decision for the site); remove coal tar from beneath an adjacent City-owned public park and swimming pool; and develop plans for and provide a temporary and permanent replacement swimming pool facility. The order provides for close coordination of work by National Grid with work required by EPA's 2016 consent order with New York City addressing the property acquisition, design of the CSO retention tank, and related matters. Finally, the Order provides for the reimbursement of EPA's oversight costs.

"General Duty Clause" Compliance Order Issued to Shamrock Enterprises
On 5/29 Region 2 issued an order regarding Shamrock's failure to comply with §112(r) of the Clean Air Act, known as the "general duty clause," at its Franklinville, NJ facility. At the facility, which is near residences, Shamrock sells, stores, and handles compressed gases including acetylene and propane, which are extremely hazardous substances. Shamrock failed to identify potential hazards from accidental releases, and to design and maintain a safe facility so as to prevent releases. EPA inspected the facility at the request of New Jersey; state and local agencies participated in the inspection. The Order calls for proper handling and storage of extremely hazardous substances, and compliance with applicable industry standards and safety regulations, including fire code requirements.

Chemours Chambers Works/Deepwater, NJ
Chemours responded to EPA's questions regarding GenX, and we have begun our review of the document. Within the next one to two weeks we expect to start receiving results of Chemours' sampling for GenX in nearby monitoring and residential wells starting as early as next week. NJDEP has received an Order to Show Cause initiated by the Township of Carney's Point, which is near the Deepwater facility. The Town seeks NJDEP approval of a public participation plan for the Township. Chemours has agreed to develop a public website similar to the one that was set-up for Chemours' Fayetteville, NC site; development of the website should take about a month.

Wolff-Alport Superfund Site, Brooklyn, NY
RA Pete Lopez and staff met on 5/30 with Congresswoman Nydia Velasquez to brief her on progress at this site. At her request, Region 2 will organize a public availability session to update the community about the work at the site, probably on June 18.

Upcoming Major Decisions and Events:

Confidential: Settlement with NYC Housing Authority (NYCHA)
As of this writing, the announcement of the settlement with NYCHA is expected to occur on June 5th at noon at the U.S. Attorney's Office in Manhattan. We expect that Susan Bodine will attend.

June 6: RA Pete Lopez will give keynote remarks at Columbia Law School's "Key Environmental Issues in EPA Region 2," a biennial conference co-sponsored by the American Bar Association. The conference will also feature a panel discussion among the RA and the environmental commissioners of NY, NJ, PR and the USVI.

June 7: Deputy Administrator Wheeler will be visiting Region 2, with a planned tour of Gowanus Canal.

June 18: Region 2 leadership will be participating in a Lake Guardian event in Rochester, NY to highlight the survey of Lake Ontario (dive and sampling missions by EPA staff).

Region 3

Hot Topics:

Lead-Based Paint Program Continues Outreach Efforts in Philadelphia
LCD managers and staff met with the City of Philadelphia Department of Public Health's Director of Environmental Health Services and the Program Administrator of the Lead and Healthy Homes Program to continue discussing potential partnership opportunities. The City expressed interest in working together on outreach campaigns, especially to child care centers in Philadelphia. LCD learned more about the City's laws and programs related to lead-based paint in child care centers, as well as communication channels, outreach initiatives, training sessions, and inter-agency meetings, which may provide opportunities for collaboration. LCD will speak with the City again in June to follow up on this conversation.

Administrative Settlement Executed on Delaware Sand & Gravel Landfill Superfund Site, New Castle, Delaware
An Administrative Settlement Agreement and Order on Consent (AOC) for remedial design (RD) was executed on May 22, 2018, which is 31 work days after EPA waived special notice procedures and invited the Delaware Sand & Gravel Landfill (DS&G) Remedial Trust to negotiate the agreement. Respondents to the AOC will complete pre-design investigations and the RD and install two groundwater interceptor wells to begin implementation of EPA's December 2017 Amendment No. 2 to the 1988 Record of Decision. EPA also issued letters to the potentially responsible parties at the adjacent Army Creek Landfill Superfund site to encourage their continued negotiation of an allocation agreement with the DS&G Remedial Trust for performance of the remedial action under a future consent decree.

EPA Region III Reissues DC MS4 Permit
On Wednesday, May 23, 2018, EPA reissued the Municipal Separate Storm Sewer System NPDES permit for the District of Columbia (DC MS4).
The DC MS4 permit had been administratively extended since it expired in October 2016. EPA worked closely with the District of Columbia in drafting this permit and considered numerous public comments from a variety of stakeholders. The DC MS4 permit will take effect June 22, 2018.

EPA Certified Lead Renovator Company Pleads Guilty for Failing to Follow Safe Work Practices to Reduce a Lead Hazard Exposure Under Toxic Substances Control Act (Criminal Case No. 1:18-Cr-00157 Middle District of Pennsylvania)
On May 22, 2018, Bitner Brothers Construction Company, Inc. (Bitner Brothers) of Carlisle, Pennsylvania entered a two-count plea for violating safe work practices promulgated under the Toxic Substances Control Act (TSCA), and aiding and abetting. In February 2017, Bitner Brothers conducted the work inside two apartments In Harrisburg, Pennsylvania while families with small children were present. The company failed to comply with the regulation requiring that power grinding must have a shroud or containment system equipped with a HEPA vacuum during the renovation pursuant to Title 15, United States Code, Sections 2689 and 2615(b).

As part of the plea agreement, the defendant, and its President and owner, Charles H. Bitner, Jr., were directed not to undertake new work contracts that require a special skill, training or certification related to the handling and/or management of lead, including lead-based paints, for the period of probation. Magistrate Judge Martin Carlson accepted the plea and set a sentencing date for September 18, 2018. The maximum penalty for that offense is a fine of $200,000, a maximum period of probation of five years, as well as the costs of prosecution or probation, and a special court assessment.

Upcoming Major Decisions and Events:

None.

Region 4

Hot Topics:

Daicel Safety Systems (Beaver Dam, KY)
Key Message: During the week of May 29, 2018, Region 4 Administrator Trey Glenn informed the Commissioner for the Kentucky Department for Environmental Protection that EPA will defer to the state regarding the permit for Daicel Safety Systems.

Subtropical Storm Alberto
Key Message: Region 4, in coordination with Florida, Alabama, and Mississippi, conducted an assessment to identify any impacts from the storm to wastewater treatment facilities, Risk Management Plan facilities, or Superfund sites. No issues were identified.

Kentucky 2016 303(d) List Approval
Key Message: Region 4 has determined that Kentucky's 2016 303(d) List update substantially meets the intent of section 303(d) of the CWA and the EPA's implementing regulations. The Region is approving all the changes identified by the Commonwealth of Kentucky. Specifically, Region 4 approves Kentucky's decision to include approximately 350 additional pollutant-waterbody combinations on the section 303(d) list, and concurs with the delisting of 68 pollutant-waterbody combinations, Region 4 does not anticipate objections from stakeholders or the public nor anticipates media interest.

Upcoming Major Decisions and Events:

Decisions
Grenada – The Region's position based on the information and proposed remedy submitted by the PRP.

Events
Regions 4, 6 and Gulf of Mexico Program Office Meeting
On June 4, 2018, Region 4 Administrator Trey Glenn, Region 6 Administrator Anne Idsal, and other regional senior leadership will meet to discuss future engagement and support from the Gulf of Mexico Program Office and tour ongoing projects with partner agencies. New Orleans, LA. Closed Press.

Hurricane Preparedness Meeting
On June 5, 2018, Region 4 Administrator Trey Glenn will participate in a hurricane preparedness meeting with other senior leaders from Region 4, Region 6, and various headquarters offices. New Orleans, LA. Closed Press.

Region 5

Hot Topics:

EPA Reaches Agreement in Principle with Crown Enterprises Inc. Regarding the McLouth Steel Property
Key Message: Crown Enterprises and its affiliate, MSC Land Company LLC, are expected to acquire the property, which is currently held by the Wayne County Land Bank.

The agreement will provide the companies with legal protections in exchange for cleanup work at the property. EPA, Michigan Department of Environmental Quality, U.S. Department of Justice, Crown and MSC devoted considerable time to this agreement, and EPA believes it will benefit the public by allowing for the reuse of contaminated land. EPA expects that the agreement can be finalized within the next 120 days.

EPA Responds to Office of Inspector General's Flint Report
Key Message: On May 30, 2018, Region 5, in coordination with OECA and OW, issued a formal response to the OIG's Flint report, including concurrence with all nine of the OIG's recommendations. The response also included corrections to a series of identified factual inaccuracies that were contained in the OIG's report.

The agency is working expeditiously to implement the recommendations made by the OIG.

EPA and MDEQ Coordinating on Draft Back Forty Mine Permit
Key Message: Once MDEQ shares a revised draft, the Region will send a letter to MDEQ indicating that the current draft satisfies EPA's objections if issued by June 6.

The Region agrees that the proposed conditions would satisfy EPA objections to the State's draft CWA 404 permit, and has provided suggestions to clarify the permit language. MDEQ will revise the draft to include clarifying language and will share with EPA this week.

Upcoming Major Decisions and Events:

Region 5 to Brief Administrator Pruitt on USS Lead on June 6, 2018
Key Message: The Region will be briefing Administrator Pruitt on the draft USS Lead Zone 1 Proposed Plan Record of Decision Amendment.

The USS Lead site is on the Administrator's Emphasis List and the completion of the Zone 1 Record of Decision Amendment is the completion milestone referenced for this site. Given the sensitivity of the issues within the community and the potential for the Amendment to be greater than $50 million, a briefing for the Administrator is required and is being coordinated with HQ.

EPA to Hold a Series of Public Engagement Meetings for the Great Lakes Restoration Initiative Action Plan III
Key Message: Meetings will be held in Toledo, Ohio; Rochester, N.Y.; Duluth, Minn.; Milwaukee, Wis.; Saginaw, Mich.; and Chicago, Ill., between June 13 and August 7, 2018.

EPA and its federal partners are in the process of developing GLRI Action Plan III, which outlines Great Lakes restoration focus areas and goals for the years 2020-2024. The proposed plan will be available for formal public comment this fall.

Region 6

Hot Topics:

HP Cylinders Emergency Response, Baytown, Texas
The company was called Stillwater Consultants, LLC, and it abandoned over 500 cylinders of compressed gas. EPA expects the contractor bids to begin to come in this week. Texas Commission on Environmental Quality (TCEQ) continues to provide 24-hour site security and conduct daily fence line air monitoring. All fence line readings have been non-detect to date. The site remains secured and conditions are stable, but being monitored closely. EPA's Emergency Response contractors are on standby in Houston and ready to respond in the event the situation changes.

US/Mexico Border Wall, McAllen, Texas
Under the recent appropriations bill the Secretary of Homeland Security is required to consult with the Secretary of Interior and the Administrator of the U.S. Environmental Protection Agency as they plan to replace existing and build the new wall and fence along the border. While the Secretary of Homeland Security issued waivers on many border wall/fence projects in 2017, DHS would like to address environmental health concerns upfront in the design and planning phase where possible. EPA joined federal officials to tour the Border Wall along the Lower Rio Grande near McAllen, Texas this week.

Carbon Black CAA Judicial Settlements, Oklahoma, Louisiana, Texas
On May 25, 2018, DOJ and EPA filed a motion to enter judicial settlements for the following consent decrees (CDs), all part of EPA's National Carbon Black Initiative: Cabot Corporation (2nd amendment to existing CD), Orion (CD), Columbian Chemicals (CD), and Sid Richardson (CD). In addition, Continental Carbon (amendment to existing CD), a motion to enter was filed and granted.

Sandow Power Plant, Rockdale, Texas
EPA anticipates that as early as June 4, 2018, the U.S. Department of Justice (DOJ) may notify Sandow Power Company LLC (SPC), an affiliate of Luminant Generation Company LLC, that the United States will join in a motion to the Court to terminate the Consent Decree (CD) relating to SPC's coal-fired power plant in Rockdale, Milam County, Texas. On January 11, 2018, SPC permanently retired Sandow Units 4 and 5, the subjects of the CD. On February 7, 2018, SPC sent a letter to DOJ and EPA requesting that the United States join in a motion to the Court to terminate the CD.

Anchor Glass Container Corporation, Henryetta, Oklahoma
The Department of Justice (DOJ) and EPA are expected to sign a Consent Decree (CD) with Anchor Glass Container Corporation (Anchor). The settlement includes glass facilities in Regions 2, 4, 5, and 6; two states, Indiana and Oklahoma, also participated in the negotiations and plan to sign the CD. The Anchor facility in Region 6 is located in Henryetta, Oklahoma, and the settlement resolves Clean Air Act violations for commencing construction without obtaining permits to comply with the Act's Prevention of Significant Deterioration requirements. Anchor will install air pollution control equipment and pay a $1.1-million-dollar penalty, with $650,000 going to the United States, and $325,000 going to each of Indiana and Oklahoma.

New Mexico NESHAP/NSPS Delegation
EPA withdrew its direct final approval of the updated of NESHAP and NSPS provisions to New Mexico Environment Department. EPA received adverse comments regarding NMED's ability and available resources to implement and enforce the NESHAP and NSPS standards.

Upcoming Major Decisions and Events:

St. James Parish South Louisiana Methanol LP, Louisiana

Region 6 intends to issue a federal register notice announcing the Administrator's decision on the South Louisiana Methanol Title V Petition. The date, while intended for June 15, is subject to change based on internal deliberations on the merits of the petition.

Arkansas State Implementation Plan
Region 6 intends to take final SIP action by June 20 to raise ADEQ's minor NSR permitting and de minimis thresholds. EPA received significant public comments on the proposed SIP changes from Sierra Club and more specifically on our 110(l) analysis (anti-backsliding into nonattainment) for the action. EPA has developed a response to those comments in the final action. This will address two backlog SIP actions.

June 4	RESTORE Project Tour, New Orleans, Louisiana
June 5	Hurricane Preparedness Meeting, New Orleans, Louisiana

Region 7

Hot Topics:

Sporlan Valve Site Meeting Hosted by Missouri Department of Natural Resources (MDNR)
Key Message: Region 7 attended a state organized stakeholder meeting on the potential NPL listing of the Sporlan Valve site in advance of a public availability session next week.

- On May 30, MDNR and EPA Region 7 met with Washington, MO City officials, Franklin County Commissioners, the Franklin County Health Department, and State Representatives to discuss local support for adding the Sporlan Valve site to the Superfund National Priorities List (NPL). TCE has been detected in groundwater, soil gas, and indoor air of residential homes adjacent to the site and a series of actions have been taken by EPA to mitigate the threat of vapor intrusion including sampling for TCE vapors in homes and installing vapor mitigation systems. To date, EPA has installed and/or overseen the installation of 19 vapor mitigation systems at homes adjacent to the site.
- On June 5, EPA will host a Public Availability session in Washington, MO to discuss the proposal of the site to the NPL. MDNR and the Governor of Missouri want local support for proposed listing prior to EPA moving forward.

Upcoming Major Decisions and Events:

Hurricane Preparedness Meeting
Key Message: On June 5, Regional Administrator Jim Gulliford will travel to New Orleans, LA to attend the Hurricane Preparedness Meeting.

- The purpose of the meeting is to consider and address lessons learned during prior natural disasters, most notably from the 2018 hurricane and wildfire seasons, to improve EPA's natural disaster preparedness, response, and recovery efforts.
- Several EPA regions and offices have been invited to participate.

OECA Assistant Administrator Visit
Key Message: On June 6, OECA Assistant Administrator Susan Bodine will visit Region 7. Agenda sessions include opportunities for AA Bodine to meet with Superfund and Criminal Investigation Division staff, participate in an All Hands meeting for Region 7 staff, and discuss enforcement direction.

Assistant Deputy Administrator and Chief of Operations Visit
Key Message: On June 7, Assistant Deputy Administrator and Chief of Operations Henry Darwin will be at Region 7 to assess progress and provide coaching on visual management tools created during Region 7's ELMS training in late April.

Region 8

Hot Topics:

Notice of Intent to Delete the Davenport and Flagstaff Superfund Site published in FR
On June 4, EPA and the Utah Department of Environmental Quality will invite the public to comment on the proposal to delete the remaining portions (OU2, OU3 and the remaining portions of OU1) of the Davenport and Flagstaff Smelters Superfund Site from the National Priorities List.

Upcoming Major Decisions and Events:

Site Visit to Basin Electric Laramie River Station
On June 6th, R8 staff will join the Wyoming Department of Environmental Quality at the Basin Electric Laramie River Station to learn more about NO_x emission controls being installed in accordance with a settlement agreement entered into by the EPA, the state of Wyoming and Basin Electric. In accordance with the settlement agreement, the EPA must propose by October 5, 2018, a revised Federal Implementation Plan for the Laramie River Station reflecting, among other things, the agreed upon NO_x controls.

Region 9

Hot Topics:

Hawaii Volcano Response
RA Mike Stoker met with Hawaii Governor Ige and key State leaders. We shall brief Dep. Administrator Wheeler Friday regarding our air monitoring and public communication. We plan to launch a publicly accessible website with real-time air-monitoring data (SO2, H2S, and particulates) from our 12 stations. With FEMA and HHS, we'll increase risk communication and community engagement where the County has been reticent. The State is requesting of FEMA increased federal support under ESF 8 and ESF 10 (e.g. 10 additional air monitoring stations). We're in close contact with the National Guard and Civil Support Team to address electrical power, cell phone coverage, and access to our air monitoring network.

National Oil Enforcement
We're hosting an EPA-only national oil enforcement meeting in the Regional Office, with participation from the Regions, OLEM and OECA.

Upcoming Major Decisions and Events:

Nevada
On June 5-6, RA Mike Stoker will host the Nevada Dept. of Environmental Quality executive team for two days of program meetings in San Francisco.

Arizona
June 6-7, RA Mike Stoker with participate in the Sen. McCain-hosted Rio Salado tour and meetings with Federal and State agencies, to focus on improving the environmental and economic vitality of the Salt River riparian corridor. On June 7, he'll meet with Arizona DEQ Director Misael Cabrera and present the newly awarded Performance Partnership Grant.

So. California
June 8-9, RA Mike Stoker will meet with the EPA San Diego Border Office staff and be briefed on our Mexican Border program. He will address the California Independent Petroleum Association annual conference.

American College of Environmental Lawyers
Alexis Strauss will speak June 1 at the San Francisco regional meeting of this group, which convenes in each Region and has in recent months hosted speaking engagements with Ken Wagner and Cathy Stepp.

Region 10

Hot Topics:

Region 10 Assists Salem, OR With Harmful Algal Bloom Event and Do-Not-Drink Advisory
A harmful algal bloom has produced high concentrations of microcystins in Detroit Lake, which serves as the primary drinking water source for the City of Salem, Oregon. A recreational water advisory was issued for the lake on May 23rd, when concentrations of microcystins were measured at more than 10 times the Oregon Health Authority advisory level. Out of an abundance of caution on May 29, the City issued a do-not-drink advisory for individuals with compromised immune systems and small children. An advisory update will be issued after additional sample results come in on May 31st. EPA's role is to provide technical assistance to the state and City of Salem and answer questions related to HABs effects and treatment options. Over the past several years, Region 10 has worked to build capacity among states, tribes and local governments to identify HABs problems, the role of nutrients, and response actions, including hosting workshops and webinar-based meetings. Region 10 is following the draft HABs Response Plan template to manage our coordinated response to this incident with HQ, state, and local officials.

Upcoming Major Decisions and Events:

Region 10 Approves Idaho's NPDES Program
On June 5th, Region 10 and EPA headquarters will participate in a signing ceremony in Boise, Idaho announcing EPA's approval of the Idaho Department of Environmental Quality's wastewater discharge permit program (IPDES). Starting July 1, 2018, IDEQ will begin issuing and enforcing water pollution permits for industry and municipalities across the state. IDEQ has been working for several years to build a program that will ensure dischargers meet the state's water quality standards and protect water quality. The program will be phased in over four years and Region 10 will continue to provide technical assistance.

Region 10 Participates in Regional Tribal Operations Committee Quarterly Meeting in Juneau, AK
The Region 10 Tribal Operations Committee will meet from June 5th-7th in Juneau, Alaska. Agenda topics include updates from EPA headquarters and Region 10 leadership on water quality standards and fish consumption rates, drinking water and the Backhaul Alaska Pilot Project. In addition, Tribal Operations Committee members will provide direct report outs to EPA leadership on environmental issues and concerns. Region 10's Deputy Regional Administrator and Tribal Policy Advisor will attend as well as several staff members.

EPA Leads Food Recovery Summit at CenturyLink Field in Seattle
On June 7th, Region 10 staff will facilitate a half-day food recovery summit at CenturyLink Stadium. The summits hosts hotel and restaurant chefs from King County and representatives from food recovery organizations across the state who will share best practices and opportunities for food recovery within the hospitality sector. The event is being hosted by the Seattle Seahawks, who are active participants in both EPA's Food Recovery Challenge and EPA's WasteWise partnership program. An audience of over 100 hotel and restaurant chefs, food and beverage directors, and sustainability managers are expected.

Region 10 Hosts Meeting of the Puget Sound Federal Task Force (WA)
On June 7th, Region 10 Administrator Chris Hladick will host two Puget Sound Federal Task Force meetings: one with regional federal leaders and a second with federal leaders and western Washington tribal leaders. The purpose of the regional federal leaders meeting is to report out on Puget Sound Action Plan accomplishments since Jan. 2017, and plan for an upcoming Federal Task Force leadership meeting later this summer in Washington, D.C. The joint federal/tribal leaders meeting is being convened to discuss updates on the Western Washington Treaty Rights at Risk issues, report out on Puget Sound Federal Task Force Action Plan accomplishments as they relate to tribal priorities, and provide an opportunity for new tribal and federal leaders to coordinate and strategize on how best to work together.

Office of Administration and Resources Management

Hot Topics:

Workgroups Established to Implement New Executive Orders
On May 25, 2018, President Trump issued three new executive orders impacting: 1) collective bargaining; 2) union official time and space; and 3) employee accountability. OARM has established three agency-wide workgroups to evaluate the executive orders and their impact on EPA, and develop recommended action plans for EPA compliance with the executive orders.

Employee Viewpoint Survey Results
As of May 29, 2018, EPA's agency-wide Employee Viewpoint Survey response rate was 36%. The government-wide response rate is 26%. Employees are encouraged to complete the survey by June 12, 2018.

Upcoming Major Decisions and Events:

None.

Office of Air and Radiation

Hot Topics:

- **Tracking SIP Actions:**
  - Total Number of SIPs submitted to Regions in FY 2018: 199
  - Total Number of SIP Submittals with Final Action taken by the Regions in FY 2018: 157
  - Total Number of Pending SIPs: 765

- **Packages at OMB for Review:**
  - Oil and Natural Gas Sector: Emission Standards for New, Reconstructed, and Modified Sources Reconsideration (Proposed Rule)
  - NESHAP: Surface Coating of Large Appliances; Printing, Coating, and Dyeing of Fabrics and Other Textiles; and Surface Coating of Metal Furniture RTR (Proposed Rule)
  - Protection of Stratospheric Ozone: Revisions to the Refrigerant Management Program's Extension to Substitutes (Proposed Rule)
  - Renewable Fuel Standard Program: Standards for 2019 and Biomass-Based Diesel Volume for 2020 (Proposed Rule)

- **Packages that will move soon to OMB for Review:**
  - Repeal of Emission Requirements for Glider Vehicles, Glider Engines, and Glider Kits (Final Rule)

- **Packages that will move soon to Signature:**
  - Health and Environmental Protection Standards for Uranium and Thorium Mill Tailings (Withdrawal of Proposed Rule)

Upcoming Major Decisions and Events:

Ozone Transport Commission (OTC)
Next Wednesday, Bill and Clint will be attending the OTC Executive Session in Baltimore. (The OTC is a multi-state organization created under the Clean Air Act that is responsible for advising EPA on transport issues and for developing and implementing regional solutions to ground-level ozone issues in the Northeast and Mid-Atlantic regions).

Office of Chemical Safety and Pollution Prevention

IMPORTANT DEADLINES

Row	Determination Type	Pending on 5/29/2018	Determinations Completed[1] as 5/29/2018	Determinations Posted on the Website as of 5/29/2018[6]
1	# of "not likely" determinations	**1**	**122**[4]	**122**[4]
2	# of §5(e) Orders signed by both EPA and the submitter	-	**400**	**399**
3	# of §5(e) Orders signed by EPA and awaiting submitter signature	**41**	-	-
4	# of non-Order SNURs/"not likely" determinations	**0**	**0**	**0**
5	# of cases in post-FOCUS final determination development[5]	**318**[3, 5]	-	-
6	# of cases flagged for in-depth review	**43**	-	-
7	# of PMNs, SNUNs and MCANs awaiting FOCUS (within 90-day review)	**30**	-	-
8	# of LVE/LOREX exemption grants	-	**602**	**597**
9	# of LVE/LOREX exemption denials	-	**121**	**120**
10	**Total number of cases**	**433**	**1245**	-
11	Normal active workload for the New Chemicals Program	300	-	-
12	Number of cases undergoing testing or data development by submitter	74[3]	-	-
13	**Backlog**[2]	59	-	-

[1]"Determinations Completed" means that EPA has completed its reviews on these cases and that final determinations have been made by EPA under TSCA section 5(a)(3).

[2] (Total number of cases) – (Normal active workload for the New Chemicals Program) - (Number of cases undergoing testing or data development) = Backlog

[3] Of these cases, approximately 72 are "active" lung toxicity cases that are suspended while submitters either conduct or are deciding whether to conduct testing to develop data on pchem properties, exposures and toxicity.

[4] "Not Likely" determinations are not posted until the final signed determination document is prepared and has been shared with submitter.

[5] These cases are those for which Post-FOCUS work is underway to develop: not likely determinations; non-Order SNURS coupled with not likely determinations; or section 5(e) or 5(f) Orders. When the OPPT Office Director decides which of these regulatory paths to follow, the case is moved to: Row 3 when the section 5(e) or 5(f) Order is sent to the submitter for signature; Row 4 when the SNUR is published and the not likely determination document is signed; and Row 1 when the determination document is sent to the OPPT OD for signature.

[6] These are all only final determinations posted on the web: grants and denials.

Hot Topics:

Problem Formulations for First 10 Chemicals Selected for Risk Evaluation under Toxic Substances Control Act (TSCA)

On June 1, OCSPP released the problem formulation documents for public comment on the first 10 chemicals selected for risk evaluation under the amended TSCA. Asbestos, methylene chloride, 1,4-dioxane, tricholoroethylene, and cyclic aliphatic bromide cluster (HBCD) are among the first of the chemical problem formulations that were released. EPA intends to finalize these ten risk evaluations by December 2019. OCSPP

is also releasing a systematic review approach to share with the public the methodology that the TSCA program will use to ensure that the best available science is relied upon in these and other risk evaluations.

EPA Announces a Significant New Use rule (SNUR) for Certain Uses of Asbestos
EPA is proposing a SNUR for certain uses of asbestos (including asbestos-containing goods) that, when final, will require manufacturers and importers to notify EPA before starting or resuming manufacturing, importing or processing of asbestos.

Upcoming Major Decisions and Events:

The Full State FIFRA Issues Research and Evaluation Group (SFIREG) Meeting
On June 4-5, Ed Messina, Acting Deputy Director of the Office of Programs and several staff will present at the Full State FIFRA Issues Research and Evaluation Group (SFIREG) meeting on various topics, including Cooperative Federalism – Implications for State Pesticide Regulatory Programs, Pollinator Protection Activities, Dicamba, and ESA BiOp Update.

12th Antimicrobial Workshop
On June 7-8, the Office of Pesticide Program's will host the 12th Annual Antimicrobial Workshop at the Renaissance Arlington Capital View Hotel in Arlington, VA. Topics planned for discussion include, the Antimicrobial Testing Program, Updates to Electronic Submission Portal, Emerging Viral Pathogens, Update on 810 Guidelines, SmartLabel and e-CSF, and Registration Review Updates.

Office of the Chief Financial Officer

Hot Topics:

- EPA has received a total of $3.2 million from the Federal Emergency Management Agency to support FEMA's response to the Lava Flows/Volcano Eruption in Hawaii.
- OCFO continues to coordinate with the agency to review responses to House Appropriations Committee's FY 2019 budget hearings Questions for the Record (QFRs) and is reviewing the Senate Appropriations Committee's hearing transcript. OCFO expected SAC QFRs to arrive this week but those QFRs have not yet arrived.
- The HAC Full Committee mark-up of EPA's FY 2019 appropriations bill is scheduled for June 6. SAC Subcommittee and Full Committee markups are scheduled for the week of June 11.

Upcoming Major Decisions and Events:

- NPM feedback on draft materials for the FY 2018 second quarter Administrator's Performance Review were due to OCFO May 31. OCFO will consolidate and vet through the COO. The Quarterly Performance Review is scheduled for June 19 from 3-5 pm and includes all AAs and RAs.
- OPA is reviewing EPA's final draft FY 2018 second quarter Agency Priority Goal (APG) Action Plans, which address minor OMB comments. Once OPA approval is received, OCFO will provide final draft plans to OMB to meet its June 8 deadline. OMB target date for posting second quarter updates on publicly available website is June 14.

Other

- The OMB/EPA Strategic Review meeting is set for June 19 from 1-2:30 pm to discuss results of EPA senior leader assessments of progress toward the Strategic Plan, including risks to achieving strategic objectives, and management priorities focused on EPA Lean Management System deployment. OCFO is working with OMB and the Deputy Administrator's office to finalize meeting logistics. In addition to the Deputy Administrator, expected EPA participants include the COO, CFO, and AAs/DAAs (or equivalent) for OCIR, OP, OGC, OARM, and OITA.

Office of Congressional and Intergovernmental Relations

Hot Topics:

June 7 - House Energy and Commerce Committee, Subcommittee on Energy will hold a hearing on: Hydropower Licensing and Water Quality Certification under CWA 401
(Witness: John Goodin, OW) and other agencies, 11 am, 2123 Rayburn

Upcoming Major Decisions and Events:

- **June 4** – Small Communities Advisory Subcommittee will have an introductory teleconference Monday at 2pm. Ken Wagner, Senior Advisor to the Administrator for Regional and State Affairs is scheduled to speak with the newly appointed and current members.
- **June 5** – Notification of Idaho NPDES transfer of authority
- **June 6**- Quarterly Outreach meeting with Intergovernmental Associations will feature an introduction of EPA Deputy Administrator Andrew Wheeler, and an opportunity for brief engagement with the representatives of attending Intergovernmental Associations. Part II of the meeting will focus on "The Federal Strategy to Reduce Childhood Lead Exposure." Dr. Hayley Hughes, EPA National Lead Coordinator, Office of the Administrator, will provide updates, and engage in dialogue with the group.
- **June 6** – House Energy and Commerce member briefing on PFAS four-step action plan w/OW, OLEM, OCSPP, ORD
- **June 6&7** – Senator McCain, Rio Salado Federal Partners Tour, Tempe AZ
- **June 8** - US Conference of Mayors 86th Annual Meeting in Boston, MA
- **June TBD** – Senator Baldwin staff call on PFAS actions w/OW
- **June TBD** – Congressman Latta staff and HEC staff briefing on HABs in drinking water
- **June TBD**- Congressman Doyle staff briefing re: PFAS actions
- **TBD** – Cong. Peters (CA) TA re Point Loma WWTP legislation w/OW, OGC, R9
- **TBD** – Sen. Tester (MT) staff briefing on Elk River Watershed w/OW, R8
- **TBD** – Sen. Isakson (GA) staff briefing on new chemicals process w/OCSPP
- **TBD** – Approps staff briefing on PRIA fees w/OCSPP, OCFO
- **TBD** - SEPW/HEC staff briefing on TSCA first 10 chemical problem formulations w/ OSCPP

Office of Enforcement and Compliance Assurance

Hot Topics:

Construction Company Pleads Guilty for Not Following Lead Rules
On May 22, 2018, Bitner Brothers Construction, Inc. pleaded guilty in the Middle District of Pennsylvania on one count of violating TSCA and one count of Aiding and Abetting. Both Bitner Brothers Construction and owner Charles H. Bitner, Jr. will forfeit their lead certification licenses. Bitner Brothers Construction, Inc. is in the business of conducting residential and commercial renovations, repairs, and painting. Bitner Brothers did not follow required work practice standards during the replacement of windows in an apartment complex located in Harrisburg, Pennsylvania in early 2017.

Five Pennsylvania Men Charged with Conspiring to Defraud the U.S. and Violate the Clean Air Act
On May 25, 2018, Gavin Rexer, Dennis Paulhamus, Timothy Sweitzer, Joseph Powell, and John Joseph were charged with conspiring to impede the lawful functions of the EPA and DOT and to violate the Clean Air Act. Rexer, Powell, and Joseph were employees of Rockwater Northeast, a company that serviced the fracking industry. In the course of their employment, they conspired to modify the emissions systems on approximately 30 Rockwater heavy-duty diesel trucks by using "defeat devices." The defeat devices were obtained from Paulhamus and Sweitzer and their purchases were concealed in Rockwater's books and records by mislabeling them as exhaust systems. The conspirators also are accused of taking the modified commercial motor vehicles to state approved inspection stations, including Sweitzer's Garage, to pass federally regulated commercial motor vehicle inspections falsely.

Army Pays Stipulated Penalty to Resolve Violations at the Umatilla Army Depot
On May 14, 2018, the United States Army paid a stipulated penalty of $125,000 to EPA to resolve violations of the CERCLA Federal Facilities Agreement (FFA) for the Umatilla Army Depot after receiving a Congressional appropriation for the penalty. On July 14, 2016, EPA Region 10, the Army, and the Oregon Department of Environmental Quality signed a settlement agreement to resolve violations set forth in a November 2, 2015, Notice of Violation. The Army's failed to comply with several remedial action requirements contained in the Workplan for Munitions and Explosives of Concern. The settlement agreement included a new schedule and technical approach for the work remaining to be done at Umatilla along with an agreement that the Army would pay a stipulated penalty of $125,000 after it obtained Congressional authorization to pay the penalty.

Upcoming Major Decisions and Events:

On June 6, 2018, OECA AA Susan Bodine, PDAA Larry Starfield, and DAA Patrick Traylor will travel to EPA Region 7 to meet with the RA/DRA and senior enforcement managers in Region 7 to discuss enforcement and compliance priorities and issues.

On June 5, 2018, OECA DAA Patrick Traylor will join other EPA leaders in New Orleans, Louisiana to discuss hurricane preparedness for 2018, including lessons learned from recent natural disasters.

Office of Environmental Information

Hot Topics:

E-Enterprise for the Environment Launches Be Well Informed – a State-developed Shared Service
Brief description: On June 6, private well owners in New Hampshire and Wyoming will have a new web-based tool to help them understand their well water test results. Originally built by the New Hampshire Department of Environmental Services, in collaboration with their Department of Information Technology, OEI adapted the tool to enable states, tribes, and territories to use this capability to develop their own tools for private well owners with minimal development costs.
Who benefits or cares: Private well owners in participating states, Commissioners with well water programs, and state environmental agencies who are responding to citizen inquiries regarding their well water.
Why this is important: The tool demonstrates how collaborative innovation and E-Enterprise can:

- Reduce costs to E-Enterprise partners (states, tribes and EPA).
- Provide consistent, timely, and actionable information to citizens.

Additional information:

- Massachusetts, Minnesota, Vermont and Michigan are working towards adopting the tool; other states and tribes have expressed interest.
- This work was partially supported by E-Enterprise funding provided by OCFO.
- As E-Enterprise resources allow, OEI will work with other states/tribes/territories to support this shared service.

Upcoming Major Decisions and Events:

None.

Office of General Counsel

Hot Topics:

- *Charles A. Folsom v. USACE*, No. 4:17-cv-3143 (D. Neb.). New development: On May 30, Charles Folsom, a Nebraska landowner, filed a notice of appeal to the US Court of Appeals for the Eighth Circuit challenging a decision from the US District Court for the District of Nebraska granting EPA's motion to dismiss his challenge to pre-enforcement activities by EPA and the Corps regarding the placement of fill into the Elkhorn River. EPA sent Mr. Folsom a proposed compliance order and invited him to negotiate and Mr. Folsom declined and sued EPA and the Corps to enjoin them from bringing any enforcement action. The District Court dismissed the complaint.
- *Ctr. for Envtl. Health v. Pruitt,* No. 3:18-cv-03197 (N.D. Cal). New development: On May 30, three NGOs filed a complaint against EPA and FWS for failing to comply with section 7 of the ESA with respect to the registration or reregistration of 21 pesticide products containing the active ingredient malathion. Plaintiffs assert that EPA and FWS have failed to meet their substantive duty to ensure that the malathion products do not jeopardize endangered and threatened species, and that EPA and FWS's agreement to indefinitely extend the current ESA consultation on malathion is unlawful.
- *Ctr. For Biological Diversity v. EPA,* No. 1:18-cv-1219 (D.D.C.). New development: On May 25, Plaintiff filed a FOIA lawsuit alleging that EPA has not responded to five FOIA requests and one FOIA fee waiver administrative appeal. The FOIA requests sought all communications to or from Administrator Pruitt including emails, text messages, and phone logs generally, and on a variety of topics including ethics, "sue and settle," encrypted messaging and email records management.
- *Husch Blackwell v. EPA*, No. 1:18-cv-1213 (D.D.C.). New development: On May 25, the law firm, Husch Blackwell, filed a FOIA lawsuit alleging that EPA failed to respond to a FOIA request within the statutory time frame for a request seeking certain communications involving Jess Rowland and glyphosate or Proposition 65.
- *Sanitary Bd. of the City of Charleston, W. Virginia v. Pruitt,* No. 2:16-cv-03060 (S.D.W. Va.). New development: On May 24, Plaintiff filed a notice of appeal to the US Court of Appeals for the Fourth Circuit challenging two decisions from the US District Court, prompted by EPA's disapproval of a site-specific copper criterion that was submitted by WVDEP at Plaintiff's request. Plaintiff is challenging the District Court's rulings that (1) EPA did not have a mandatory duty to approve the site-specific criterion and (2) Plaintiff lost standing to challenge the disapproval when WVDEP issued the facility a new permit, which did not impose any copper limits on its discharge.
- *Dine' Citizens Against Ruining the Env't v. EPA*, No. 18-71481 (9th Cir.). New development: On May 23, five NGOs filed a petition for writ of mandamus asking the Ninth Circuit to compel EPA Region 9 to take final action on a Clean Water Act NPDES permit renewal application for the Four Corners Power Plant located on the Navajo Nation, near Farmington, New Mexico. According to the Petition, the coal-fired power plant has been operating under an expired administratively continued permit since 2006.

Upcoming Major Decisions and Events:

6/12 Hearing on EPA's motion to stay in *Ass'n of Irritated Residents v. EPA*, a deadline suit regarding EPA's failure to take action on the San Joaquin Valley Unified Air Pollution Control District's 2016 SIP addressing nonattainment requirements for the 2008 8-Hour Ozone Standard.

Office of International and Tribal Affairs

Hot Topics:

Tijuana Spill
OITA met with the new U.S. Consulate General to Tijuana to discuss the Tijuana spill, International Boundary and Water Commission (IBWC), North American Development Bank and U.S.-Mexico Border Program. At our urging, the Consulate General has agreed to raise the Tijuana spill and funding for Tijuana infrastructure improvements with the local and national governments in Mexico. She also agreed to look into IBWC funding mechanisms and operations at the State Department.

Columbia River Treaty
The formal negotiations between the U.S. and Canada for the modernization of the Columbia River Treaty commenced this week. The U.S. negotiation team consists of the State Department, Interior/NOAA, and Bonneville Power. OITA and Region 10 met with the State Department to discuss the role of EPA and tribes in the negotiations, and State has agreed to involve EPA in the USG strategy sessions and ensure meaningful engagement with the tribes.

Upcoming Events and Decisions:

G7 Deputies Meeting
A Deputies Meeting will be held on June 1 to discuss the upcoming G7 Leaders' Summit in Charlevoix, Quebec on June 8-9, which includes Climate Change, Energy and Oceans session.

Premier of Saskatchewan
The Administrator will be meeting with the Premier of Saskatchewan, Canada, on June 6 to discuss Canada-U.S. environmental regulation.

North American Development Bank
OITA will be meeting with the North American Development Bank on June 4 to discuss current activities and upcoming Board of Directors meeting in Mexico.

Canadian Environmental Assessment Agency
The Canadian Environmental Assessment Agency will be meeting with OP and OITA on June 6/7 to discuss the EIA process, including transboundary impacts and tribal engagement.

Office of Land and Emergency Management

Hot Topics:

- **Coal Combustion Residuals (CCR)**. (see below)

- **Clean Air Act 112(r) Risk Management Program (RMP) Reconsideration NPRM.** The proposed rule was published in the FR on May 30. A public hearing is scheduled for June 14. The public comment period ends July 30, 2018.

- **Ongoing major Superfund NPL sites** (including Colorado Smelter, East Chicago, West Lake, Bonita Peak, Hudson River, Portland Harbor, Mississippi Phosphates, Oak Ridge, Edwards AFB, Berry's Creek, American Cyanamid).

- **CERCLA 108(b) Financial Assurance – Next Three Sectors**. We are working with OGC, OP, and the AO to plan our approach to the next three sectors.

- **PFOA and PFAS.**
  - Working with OCIR, OW, and others, we are preparing for a briefing on PFAS with House Energy and Commerce members.
  - We are working with ORD and OW to develop groundwater cleanup recommendations for PFOA and PFOS.
  - OLEM is working with the AO, OGC, OECA and other AAships to look at available statutory mechanisms for PFOA and PFOS to be "hazardous substances" under CERCLA.

- **Emergency Response.** Region 9 emergency response and the national Environmental Response Team are part of the inter-governmental effort addressing volcano activity in Hawaii. OAR and ORD are assisting OLEM and Region 9 with public messaging related to acute and chronic risk from exposure to volcanic gases. Current staffing is 24.

Upcoming Major Decisions and Events:

- **Definition of Solid Waste Vacatur.** This was published in the FR on May 30, 2018.

- **Coal Combustion Residuals**.
  - We plan to get the proposed rule to OMB next week and anticipate signature on June 14 to align with the approval of Oklahoma's CCR permitting program.
  - Georgia submitted its CCR permit program application to EPA. It is undergoing review.

- **E-Manifest**. We anticipate issuing a press release on June 29, 2018.

- **Hazardous Waste Pharmaceuticals Final Rule**. We will be briefing the AO and OP in early June.

- **Hazardous Substances Spill Prevention Proposed Rule**. We anticipate OMB clearance by June 8 to allow for signature by June 15.

Office of Policy

Upcoming Major Decisions and Events:

Meeting with Canada
On June 6-7, the Office of Federal Activities will join OITA, the State Dept., and CEQ in a meeting with representatives from the Canadian government to discuss best practices for Environmental Impact Assessment and transboundary issues.

Community Assistance Announcement
In early June, the Office of Community Revitalization plans to announce six communities selected for assistance through the Healthy Places for Healthy People program, a federal initiative that works with healthcare facilities to protect the environment, improve public health, and support reinvestment in neighborhoods.

Number of Actions to OFR this Year:

- Signed by Regions:
  - Notices: 40
  - Proposed Rules: 123
  - Direct Final Rules: 8
  - Withdrawal of Proposed Rule: 1
  - Withdrawal of Direct Final: 4
  - Final Rules: 101
- Signed by HQ:
  - Notices: 204
  - Proposed Rules: 32
  - NPRM Extension: 1
  - Withdrawal of Direct Final: 1
  - Interim Final: 1
  - Final Rules: 64

Number of Actions to OFR this Week (May 25 – May 31):

- Signed by Regions:
  - Notices: 4
  - Proposed Rules: 13
  - Direct Final Rules: 0
  - Withdrawal of Proposed Rule: 0
  - Withdrawal of Direct Final: 1
  - Final Rules: 5
- Signed by HQ:
  - Notices: 11
  - Proposed Rules: 1
  - NPRM Extension: 0
  - Withdrawal of Direct Final: 0
  - Interim Final: 0
  - Final Rules: 5

Active Interagency Reviews from OMB	
Title	**OMB Due Date**
DOL/MSHA RFI: "Retrospective Study of Respirable Coal Mine Dust Rule"	05/30/2018
FAR Case 2017-014 ANPRM: "Federal Acquisition Regulations: Use of Acquisition 360 to Encourage Vendor Feedback"	06/01/2018

USDA ANPRM: "Oil and Gas Resources"	06/01/2018
USDA ANPRM: "Locatable Minerals"	06/01/2018
DOI & DOC NPRM (Pass-back): "Endangered and Threatened Wildlife and Plants; Revision of Regulations for Interagency Cooperation"	06/01/2018

Documents Submitted to OFR from May 23 - 29, 2018		
FRL	**Title**	**Date Submitted to OFR**
9978-93-Region 4	Air Plan Approval and Air Quality Designation; SC; Redesignation of the Greenville-Spartanburg Unclassifiable Area	5/29/2018
9978-92-Region 4	Air Plan Approval; South Carolina; Regional Haze Plan and Prong 4 (Visibility) for the 2012 PM2.5, 2010 NO2, 2010 SO2, and 2008 Ozone NAAQS	5/29/2018
9978-90-Region 4	Air Plan Approval and Air Quality Designation; AL; Redesignation of the Etowah County Unclassifiable Area	5/29/2018
9978-72-Region 8	Interstate Transport Prongs 1 and 2 for the 2010 Sulfur Dioxide (SO2) Standard for Colorado, Montana, North Dakota, South Dakota and Wyoming	5/29/2018
9974-26-Region 8	North Dakota Final Authorization and Incorporation by Reference of Approved State Hazardous Waste Management Program	5/29/2018
9978-73-OEI	Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting	5/29/2018
9978-77-ORD	Ambient Air Monitoring Reference and Equivalent Methods; Designation of One New Reference Method	5/29/2018
9977-72-OAR	Additional Air Quality Designations for the 2015 Ozone National Ambient Air Quality Standards	5/29/2018
9978-94-Region 4	Approval of TN Plan for Control of Emissions from Commercial and Industrial Solid Waste Incineration Units	5/25/2018
9978-87-Region 5	Air Plan Approval; Ohio; Cleveland, PM2.5 Attainment Plan	5/25/2018
9978-86-OAR	Proposed Information Collection Request; Comment Request on Two Proposed Information Collection Requests	5/25/2018
9978-80-Region 7	Delegation of Authority to the States of Iowa; Kansas; Missouri; Nebraska; Lincoln-Lancaster County, NE; and City of Omaha, NE, for New Source Performance Standards (NSPS), National Emission Standards for Hazardous Air Pollutants (NESHAP) Including Maximum Achievable Control Technology (MACT) Standards	5/25/2018
9978-56-Region 3	Approval and Promulgation of Air Quality Implementation Plans; Maryland; Continuous Opacity Monitoring Requirements for Municipal Waste Combustors	5/25/2018
9977-76-OCSPP	Pesticide Emergency Exemptions; Agency Decisions and State and Federal Agency Crisis Declarations	5/25/2018
9977-62-OCSPP	Defensin Proteins Derived from Spinach in Citrus Plants; Temporary Exemption from the Requirement of a Tolerance	5/25/2018
9976-99-OCSPP	Product Cancellation Order for Certain Pesticide Registrations and Amendments to Terminate Uses	5/25/2018
9978-74-Region 4	Public Water System Supervision Program Revision for the Commonwealth of Kentucky	5/25/2018

9978-82-Region 9	Air Quality State Implementation Plans: Arizona; Approval and Conditional Approval of State Implementation Plan Revisions; Maricopa County Air Quality Department; Stationary Source Permits	5/25/2018
9977-80-Region 8	National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List: Deletion of the Davenport and Flagstaff Smelters Superfund Site	5/25/2018
9978-81-Region 9	Approval and Promulgation of Air Quality Implementation Plans; Nevada; Rescission of Regional Haze Federal Implementation Plan for the Reid Gardner Generating Station	5/25/2018
9978-79-Region 7	Approval of Nebraska Air Quality Implementation Plans; Title 129, Chapter 20, Particulate Emissions; Limitations and Standards	5/24/2018
9978-78-Region 7	Approval of Missouri Air Quality Implementation Plans; Infrastructure SIP Requirements for the 2012 Annual Fine Particulate Matter (PM2.5) National Ambient Air Quality Standard Interstate Transport	5/24/2018
9978-27-Region 1	Air Plan Approval; New Hampshire; Nonattainment Plan for the Central New Hampshire Sulfur Dioxide Nonattainment Area	5/24/2018
9978-26-Region 1	Air Plan Approval; Connecticut; Volatile Organic Compound Emissions from Consumer Products and Architectural and Industrial Maintenance Coatings	5/24/2018
9977-56-OLEM	Response to Vacatur of Certain Provisions of the Definition of Solid Waste Rule	5/24/2018
9978-49-OECA	Proposed Information Collection Request; Comment Request; See Item Specific ICR Titles Provided in the Text	5/24/2018
9974-81-OEI	NESHAP for Beryllium Rocket Motor Fuel Firing (Renewal)/ICR No.1125.0	5/24/2018
9975-90-OEI	NSPS for Glass Manufacturing Plants (Renewal)/ICR No.1131.12	5/24/2018
9978-66-Region 5	Adequacy Status of the Indiana Portion of the Chicago-Naperville, IL-IN-WI Area for the Submitted 2008 Ozone Standard Fifteen Percent Rate of Progress Plan for Transportation Conformity Purposes	5/24/2018
9978-61-Region 5	Air Plan Approval; Michigan; Regional Haze Progress Report	5/23/2018
9978-59-Region 4	Air Plan Approval and Air Quality Designation; KY; Redesignation of the Kentucky Portion of the Louisville Unclassifiable Area	5/23/2018
9978-57-Region 3	Approval and Promulgation of Air Quality Implementation Plans; Virginia; Emissions Statement Rule Certification for the 2008 Ozone National Ambient Air Quality Standard	5/23/2018
9978-18-Region 9	Approval of California Air Plan Revisions; Butte County Air Quality Management District; Stationary Source Permits	5/23/2018
9976-24-OCSPP	Agency Information Collection Activities; Proposed Renewal of Several Currently Approved Collections (EPA ICR Nos. 2491.04 and 2475.03); Comment Request	5/23/2018
9978-69-OEI	EPA's In-Use Vehicle and Engine Testing Programs, ICR No. 0222.11	5/23/2018
9978-68-OEI	NESHAP for Group I Polymers and Resins (Renewal)" ICR No. 2410.04	5/23/2018
9978-60-OEI	NESHAP for Pharmaceuticals Production (Renewal)/ICR No. 1781.08	5/23/2018

9976-72-Region 6	Clean Air Act Operating Permit Program; Petitions for Objection to State Operating Permit for ExxonMobil Corporation, ExxonMobil Baytown Refinery, Harris County, Texas	5/23/2018
9978-58-ORD	EPA Board of Scientific Counselors Notice of Charter Renewal	5/23/2018
9978-53-OLEM	Agency Information Collection Activities; Proposed Collection; Comment Request; Continuous Release Reporting Regulations (CRRR) under CERCLA 1980 (Renewal); EPA ICR No. 1445.13, OMB Control No. 2050-0086	5/23/2018
9978-54-OW	Extension of the Application Deadline Date for Credit Assistance under the Water Infrastructure Finance and Innovation Act (WIFIA) Program	5/23/2018
9978-75-Region 10	Air Plan Approval; Washington; Regional Haze Progress Report	5/23/2018

Office of Research and Development

Hot Topics:

***Fentanyl Fact Sheet* for On-Scene Coordinators**
Nearly half (over 19,000) of the opioid-related deaths in the U.S. in 2016 involved fentanyl. EPA and state-level responders have emphasized the lack of comprehensive information on the detection, sampling, analysis and decontamination for the fentanyl class of synthetic opioid chemical compounds. ORD partnered with Office of Emergency Management's CBRN Consequence Advisory Division and Environmental Response Team, Region 5, and others to develop *the Fentanyl Fact Sheet*. It is living document that compiles current, publicly-available information for use by EPA OSCs, and may also be useful to local/state first responders such as EMT, hazmat, and law enforcement. ORD's research underway on fentanyl sampling methods and decontamination will strengthen the fact sheet over time.

Technical support on Tularemia to the Kentucky Department of Public Health
ORD is supporting the Kentucky Department of Public Health in their response to a tularemia outbreak in Butler County, Kentucky. The causative agent of tularemia, *Francisella tularensis*, is classified as a Tier 1 Select Agent by the U.S. government due to its low infectious dose, ease of spread by aerosol, and high virulence. This outbreak has affected cottontail rabbits, Beagle handlers, and Beagle dogs residing in a 240-acre beagle field trial ground. Humans can be infected with the organism by contact with infected animals or vectors. To better understand the cause of the outbreak, ORD is guiding Kentucky Department of Public Health on sampling and analysis of *Francisella tularensis* in environmental samples, and providing advice on collection and stabilization of water samples and possible causes of the outbreak.

IRIS Assessment Released for Review
On May 30th, the draft assessment for hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX) was released for post-peer review Interagency and Agency review.

Upcoming Major Decisions and Events:

We look forward to hosting OCSPP leadership in RTP on June 8 where we will discuss ORD data, methods, and tools being developed to support TSCA prioritization. On June 5th ORD staff will kick off summer with an evening of baseball at National's Park.

Science Advisory Board Meeting
On June 1st, ORD will provide an update on IRIS at the Science Advisory Board meeting. ORD will also present an overview of lead science that highlights seven success stories. Other participants and presenters include the Office of the Administrator on the Federal Lead Strategy, Office of Water, Office of Land and Emergency Management, and Office of Chemical Safety and Pollution Prevention.

Office of Water

Hot Topics:

Georgia Nonpoint Source Pollution Control Program
Today, Dave Ross co-signed a joint EPA/NOAA Federal Register Notice announcing the agencies' intent to fully approve the Georgia Coastal Nonpoint Pollution Control Program. The notice invites public comment on the agencies' proposed finding that Georgia has satisfied all conditions on the 2002 approval of the State's coastal nonpoint pollution control program. The Coastal Zone Act Reauthorization Amendments directs states and territories with coastal zone management programs previously approved under Section 306 of the Coastal Zone Management Act to develop and implement coastal nonpoint programs, which must be submitted to the federal agencies for approval. The notice will be sent to NOAA next for signature. Once published, the notice will open a 30-day public comment period.

WIFIA
As part of OW's enhanced outreach strategy to promote the 2018 Notice of Funding Availability (NOFA) opportunity, this week, the WIFIA program hosted the WIFIA Letter of Interest Submission and Selection Process Question and Answer Session. More than 70 people participated in the event. The next webinar, scheduled for June 4, will provide an overview of the WIFIA program and the 2018 selection round. In addition, OW, working with OPA, provided the regional public affairs directors with a "pitch" packet to use with local media outlets as well as key messages to fold into senior leadership speeches. Tomorrow, the WIFIA staff will present at the New England Environmental Business Council Infrastructure Workshop: Update and Overview of WIFIA Water Infrastructure Loan Program.

Environmental Financial Advisory Board (EFAB) Membership Package
This week, the EFAB's 2018 Official Membership Package was approved and is moving forward for the Administrator's signature. The package includes a new recommended chair, 4 new EFAB member appointments, and 3 departures. The term for appointees will run for a period of two years beginning June 15.

Waterkeeper II Steam Electric FOIA
This week, OW provided the May interim release for this FOIA to the requestor. The EPA was under court order to complete this FOIA by May 31st, however, the court granted an extension of that deadline to June 21, 2018.

Upcoming Major Decisions and Events:

HEC Hearing
Next week, John Goodin, Acting Director for the Office of Wetlands, Oceans and Watersheds, will testify before the House Committee on Energy and Commerce (HEC), Energy Subcommittee. He will testify to the EPA's role on the CWA section 401 state delegated authority and water quality certification process in relation to the non-federal hydropower licensing process. The panel is comprised of officials from FERC, NOAA, FWS, and USACE. The hearing is open to press.

EPA-National Tribal Water Council Meeting
Next week, Benita Best Wong will provide the opening remarks for the Council meeting and discuss with members' water issues in Indian country. This meeting is closed to press.

Public Meeting on Unregulated Contaminants in Drinking Water
Next week, the EPA will host an all-day public meeting and webinar at EPA-Cincinnati. Approximately 300 participants have registered for the meeting which will include presentations from the Technical Support Center in Cincinnati and ORD on the EPA drinking water method development and include discussion with stakeholders on innovative analytical testing procedures for unregulated contaminants.